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Papers Presented at the 1960 Meeting, Division of Food, Drug and Cosmetic Law, American Bar Association

Introduction and Index of the Latin-American Food Code

Food Additives: Food Protection Committee Activities . . . . PAUL E. JOHNSON

See Table of Contents for Articles in This Issue

A COMMERCE CLEARING HOUSE PUBLICATION

PUBLISHED IN ASSOCIATION WITH THE FOOD LAW INSTITUTE, INC.

The editorial policy of this JOURNAL is to record the progress of the law in the field of food, drugs and cosmetics, and to provide a constructive discussion of it, according to the highest professional standards. The FOOD DRUG COSMETIC LAW JOURNAL is the only forum for current discussion of such law and it renders an important public service, for it is an invaluable means (1) to create a better knowledge and understanding of food, drug and cosmetic law, (2) to promote its due operation and development and thus (3) to effectuate its great remedial purposes. In short: While this law receives normal legal, administrative and judicial consideration, there remains a basic need for its appropriate study as a fundamental law of the land; the JOURNAL is designed to satisfy that need. The editorial policy also is to allow frank discussion of food-drug-cosmetic issues. The views stated are those of the contributors and not necessarily those of the publishers. On this basis, contributions and comments are invited.

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FOOD DRUG COSMETIC LAW JOURNAL

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REPORTS

TO THE READER

Meetings

FDA-FLI Conference. — The 1960 Joint National Conference of the Food and Drug Administration and The Food Law Institute will be held in the Auditorium of the United States Department of Health, Education, and Welfare, Washington, D. C., on November 28-29, 1960. The American Medical Association, the Association of Food and Drug Officials of the United States, the Food Protection Committee of the National Research Council, the Food Additives Committee of the Manufacturing Chemists' Association, the Food Additives Committee of the Institute of Food Technologists, The Nutrition Foundation, Inc., and The Packaging Institute, Inc., are cooperating in this conference.

The morning session, held on November 28 beginning at 9:30 a. m., will be presented by the Food and Drug Administration, with Commissioner Larrick acting as moderator. In the afternoon an industry panel discussion will be held at 2 p. m., with Dr. Bernard L. Oser acting as moderator. These sessions will review recent developments relative to the food-additives amendment, the color-additive amendments, the Hazardous Substances Labeling Act, and food and drug legislation in prospect for 1961.

On November 29 at 9:30 a. m. a consumer panel, with Dr. Charles Glen King, executive director of The Nutrition Foundation, acting as moderator, will discuss various aspects of the food law from the standpoint of the consumer. The concluding session, held at 2 p. m. on that day, will consist of a question-and-answer panel. This "bread and butter" session offers an authoritative discussion of current problems. Mr. Franklin M. Depew, president of The Food Law Institute, will act as moderator.

Other speakers at the conference include Dr. Philip L. White of the American Medical Association; Dr. M. R. Clarkson of the Agricultural Research Service, United States Department of Agriculture; Chancellor Emil Mrak of the University of California, representing the Food Protection Committee; Mr. Charles W. Kaufman of the National Dairy Products Corporation; Dr. Richard S. Gordon of the Monsanto Chemical Company, representing the Manufacturing Chemists' Association; Mr. James D. Kittelton of the Manufacturing Chemists' Association; Mr. Joseph D. Becker of the Allied Chemical & Dye Corporation, representing the Manufacturing Chemists' Association; and Dr. Robert Johnson of The Kroger Company, representing The Packaging Institute.

At the informal dinner to be held in the Crystal Ballroom of the Sheraton-Carlton Hotel on November 28, an Award for Distinguished Service will be presented to the Food Protection Committee of the National Research Council. This award will be accepted in behalf of the Food Protection Committee by Dr. William J. Darby. Those wishing to attend the dinner should

promptly advise The Food Law Institute, 205 East 42nd Street, New York 17, New York. The charge for the dinner will be $20 per plate.

American Association for the Advancement of Science.—A symposium on the scientist's contribution to the safe use of cosmetics is scheduled for December 29, 1960, as part of the December 27-30 meeting of the Pharmacy Section of the American Association for the Advancement of Science. Marion B. Sulzberger, of the Department of Dermatology of New York University, will preside. Chairman of the Pharmacy Section of the AAAS is Joseph V. Swintosky, of Smith, Kline and French Laboratories. John E. Christian, of the School of Pharmacy of Purdue University, is secretary.

Resolution Offered by H. Thomas Austern and Unanimously Adopted by Members of the Division of Food, Drug and Cosmetic Law, Section of Corporation, Banking and Business Law, at the Eighty-third Annual Meeting of the American Bar Association.—"As Food and Drug practitioners, the members of this Division have been privileged for many years to deal professionally with the staff of the Food and Drug Administration of the Department of Health, Education, and Welfare. On occasion they have been constrained both as counsel for clients in the regulated industries and in the annual scholarly examination of Food and Drug law developments in Bar convention sessions, to disagree with legal interpretations advanced by the FDA staff and counsel. In none of this forthright disagreement, however, has any member of this Division at any time challenged the integrity, competence, or complete devotion to the public interest of the FDA staff. Throughout their existence, the various organized bar association groups of Food and Drug lawyers have been gratified that the FDA is a career agency, whose staff is recruited and qualified on the basis of professional competence alone, free of political sponsorship or susceptible to being influenced either by the regulated industries or by anyone else. This Division of the American Bar Association has constantly insisted that the career status of the FDA never be impaired. We deem it appropriate at this time to do so again and to reaffirm our confidence in the integrity, administrative objectivity, and high standard of professional public service of the FDA."

Charles Wesley Dunn Memorial

Charles Wesley Dunn Memorial Fund.—A fund of approximately $10,000 has been donated to the Mary Hitchcock Memorial Hospital, Hanover, New Hampshire, to establish the Charles Wesley Dunn Memorial. The amount will become the basis of a loan fund for resident physicians at the hospital who are completing the three or four years of training after medical school required to be qualified to practice in one of the medical or surgical specialties. It is hoped that the fund will be increased through other donations.

Mr. Dunn, who was president of The Food Law Institute, Inc., chairman of the ABA Division of Food, Drug and Cosmetic Law and chairman of the editorial advisory board of this JOURNAL when he died in 1959, became interested in the resident training program of the hospital while a patient there. About 70 physicians are currently enrolled in the resident program of the hospital, which combines the facilities of the Hitchcock Clinic, the Dartmouth Medical School and the nearby Veterans Administration Hospital.

WASHINGTON-

ACTION AND NEWS

In the Food and Drug Administration

October Report of Food Seizures.—Unfit foods seized in September in 55 federal court actions totaled 1,682 tons. Of these, 1,369 tons became contaminated after interstate shipment.

The largest seizure involved 2.5 million pounds of wheat, which became water damaged in an elevator fire in Denver, August 23. The city placed an embargo on the wheat during federal investigation, to determine the extent of the damage. The owners have filed a claim to have the wheat returned for reprocessing for use as animal feed or for distilling.

Other food seizures included four actions involving 37 tons of frozen eggs. Decomposed eggs were found in each of the cases.

Approximately 16 tons of frozen pork were found decomposed during transit. Meat is under the jurisdiction of the United States Department of Agriculture, which administers the Meat Inspection Act; but products that become unfit for food use after they have left the packing houses are in violation of the Food, Drug, and Cosmetic Act.

Insect- and rodent-contaminated foods held under insanitary conditions involved 19 seizures including 34 tons of flour and mixes, ten tons of rice, two tons of nuts and beans, and 2.5 tons of raisins and cheese.

Drug and Devise Seizures.—Twelve drugs and devices were alleged to be misbranded by false and misleading claims of therapeutic benefit. Five were vitamin products promoted for the prevention and treatment of disease conditions. A misbranded scalp preparation carried no warning that use in case of rash may cause serious mercury poisoning. A drug marketed without safety clearance was promoted in booklets for the medical profession, which falsely claimed that the product was an effective treatment for inoperable cancer.

Mechanical chairs and massage devices were misbranded in accompanying literature for the treatment of arthritis and rheumatism pains. The chairs were also promoted for heart trouble, and the massagers for weight reduction.

Two products seized from a discount drug house were counterfeits of well-known brands of diuretic drugs permitted to be sold only after safety clearance, which had not been secured for the imitation tablets. In making the seizure the United States marshal was accompanied by an FDA inspector and by an FDA microanalyst who brought his equipment to the drugstore so that the counterfeit products could be distinguished from genuine products.

Twenty-two lots of prescription drugs were seized in possession of a healing-arts practitioner who was not licensed by his state to distribute or dispense prescription drugs.

Four seizures alleged composition below the purity or potency claimed on the labels of the articles.

Voluntary Actions by Industry.—Voluntary corrective actions taken by the food industry in the month of September totaled 193. Approximately 606 tons of adulterated food were destroyed or converted to feed.

A grain-storage firm skimmed off 600,000 pounds of bird-contaminated wheat in one of its warehouses. The remaining 30.9 million pounds was clean. The firm spent $2,000 to have the doors and eaves completely enclosed to prevent the entry of rodents and birds which would have caused further contamination.

Adulterated drugs destroyed in ten voluntary actions were valued at $134.511. The largest of these actions involved 83.231 bottles, valued at $123,599 wholesale, of a drug that had been recalled after it had been found to be subpotent when used in a children's hospital. At the time of the recall, the manufacturer stopped shipment of all of the product still on hand.

Plant improvements made during the month of September totaled 25 actions at a cost of $198,711.

A New York tomato-packing firm installed an extra trimming table and hired an additional 20 women pickers at the cost of $21,000 in order to keep down the incidence of drosophila fly eggs in its products.

A milling company in Michigan which had a problem with insect and rodent infestation spent $29,500 on plant improvements consisting of new equipment, removal of old equipment, structural changes and cleanup operations. In addition it instigated a new sanitation schedule that will cost $29,800 a year on a continuing basis.

Voluntary corrective actions for the month of September totaled 228.

Hurricane Donna.—When Hurricane Donna hit Florida on September 10, and continued up the East Coast, inspectors from four FDA Districts were close behind, to assist state and local food and drug officials in protecting the public from contaminated foods and drugs.

In the Florida Keys, Atlanta District Inspectors found a food store so heavily damaged that the State Board of Health ordered it burned, along with its entire stocks. Other FDA Inspectors went inland to Hardee, De Soto and Highlands Counties to check food-processing plants as well as retail stores. One plant had been canning peppers until power failure occurred and half the roof of the plant was blown off. Partially processed cans were voluntarily taken by the management to the city dump and buried. An entire trailer load of peppers, waiting to be canned, spoiled before operations could resume.

At Charleston, South Carolina, county health officers made their rounds Monday morning after the hurricane struck Sunday afternoon, and found that most of the damaged stock and perishables had already been hauled to local garbage dumps.

In Norfolk, warehouses located along the waterfront suffered the major storm damage. Virginia State Inspectors immediately embargoed water-damaged establishments, pending assessment of damages and an orderly segregation of affected merchandise.

During the height of the storm in New York City, waterfront streets looked like canals. Large amounts of food on the piers in lower Manhattan and Brooklyn were wet by wind-driven, polluted harbor water. The FDA New York District Inspectors joined the city and state authorities in an immediate survey after local embargoes had been placed on domestic products and FDA detentions on imported merchandise. Two hundred and fourteen lots of foods, including more than 2.6 million pounds of coffee and cocoa beans, and large quantities of tea, spices and miscellaneous foods awaiting import clearance were refused entry, and seizures were made of 22 lots of various foods, drugs and cosmetics destined for export before they were damaged.

When Donna moved up to Rhode Island, Boston District Inspectors assisted state and local officials in salvage surveillance. Ninety per cent of the state was without electric power, in some areas as long as 72 hours. State authorities condemned more than 21,000 pounds of food found damaged in the 743 establishments investigated.

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Administrative Policy in the Administration and Enforcement of the Food-Additives Amendment

By JOHN L. HARVEY

The Author Is Deputy Commissioner of the Food and Drug Administration. He Delivered This Paper Before the American Bar Association's Annual Meeting, August 31, 1960, in Washington, D. C.

ADMINISTRATIVE POLICY in the administration of the food-additives amendment recalls to my mind a comment which was made with regard to the amendment expanding or delimiting, as the case may be, the extent of inspection allowed under the terms of the act. In that amendment, the timely and justifiable comment was made that the word "reasonable" was used an unreasonable number of times. Possibly the words "administrative" and "administration" may likewise be too generously distributed in the title of my paper. In any event, I am assuming that the committee wishes from me a factual, if not chatty, discussion of what we have done and are doing and why we did it or are doing it in the developing phases of the application of the food-additives amendment. I shall proceed on that assumption.

When this amendment was enacted in September, 1958, our first order of business was to formulate a set of regulations for the efficient administration of this amendment. We worked over draft after draft, getting every comment that we could from all of the people in the

Food and Drug Administration and the General Counsel's office. We finally came out with proposals which were published in the *Federal Register*. There were those who thought that this job had taken too long, but from the limited number of adverse comments we received from people representing industry and from the way the final regulations have so far been found extremely helpful, I am convinced that the time we took was well spent.

A second decision which we had to make was just how we were going to operate under this food-additives amendment. Should we set up a separate unit with a complement of administrative people, chemists, pharmacologists and the like—or would some other way be better? We decided against that method of operation, but instead set up an administrative unit with the idea that the technical advice and counsel would come from the established divisions of our Bureau of Biological and Physical Sciences. From the scientific side, we think that this was the wise decision. It has had the disadvantage that we were placing an added burden on an already overloaded technical staff and we were not able to get the trained people to augment that staff as fast as we had hoped to. The way that our technical people have pitched in to handle this tremendous food-additive load, however, has been extremely gratifying and those people are due a tremendous vote of gratitude not only from the Commissioner but from the industries involved as well.

Our next step was to try to get across to the industries involved the message of what needed to be done. We accepted invitations to make a large number of speeches before industry association groups, and each of these was generally followed by a spirited question-and-answer session. We engaged in extensive correspondence with those who wanted to know about the amendment and how it affected them, and our public information office even got out a booklet to tell consumers generally about the purpose and objectives of the food-additives amendment.

GRAS Lists

While the law did not so require, we thought that it would be helpful if we could notify industry of at least some of the substances which we regarded as generally recognized as safe and thus exempt from the application of the food-additives amendment. As a trial operation, we published, in December of 1958, a substantial list of

items which we thought would be in that category; but in the light of the provisions of the Act which refer to the recognition by scientists qualified to evaluate the safety of food additives, we sent this list to over 800 scientists, getting their names from our own records, colleges, universities, and nominations by people in industry. While we were grateful for the several hundred replies which we received, we were at the same time convinced that such a special handling of the so-called "GRAS" list was not a very efficient way of doing business, since it left the proposals on our part sort of hanging fire for a good many months.

We have published a few additional proposed GRAS lists since the November 20, 1959 finalization of the original GRAS list. With these, however, we were able to conclude that the lists were getting quite wide publicity in trade and technical journals in addition to the *Federal Register* publication. It is, therefore, our purpose from now on to give a reasonable time for adverse comments on the publication of the proposed GRAS lists and then finalize them if no significant exceptions are taken.

Incidentally, I should mention that our submission of the first proposed GRAS lists to the 800 scientists somehow became interpreted as meaning that if any one of these did not know anything about any specific item on the published list, that item automatically could not be classed as GRAS. I don't know where this interpretation started, but to set the record straight a vote in the negative on the basis that a scientist did not know anything about a specific substance was counted only if that scientist were expected to know about the article. Thus, for example, if an expert in the field of oils had never heard of a preservative intended for use in oils, that would be a significant comment.

Prior Sanctions

As you know, the law also exempts substances for uses covered by prior sanctions granted under the Federal Food, Drug, and Cosmetic Act, the Federal Meat Inspection Act and the Federal Poultry Products Inspection Act; and it was proposed that we publish lists of such prior sanctions. With the exception of one short list in the packaging field we found ourselves unable to do so. There were several reasons for this. First, these sanctions had not been given with the idea that they would be the basis for a so-called grandfather clause in a 1958 law; and, thus, to get them all together would call for a very

costly search of all our files. Second, some of these sanctions involved formulations which might well be classed as trade secrets and thus entitled to protection. We have made it plain, however, that if anyone believes that his product has a prior sanction for a specific use and will make inquiry of us, giving us the name of the firm to whom the sanction is believed to have been given, we will check our record on that particular firm and let the inquirer know.

When March 6, 1960—the fully effective date of the Act—approached, we were extremely disappointed at the small number of petitions for regulations which had issued. We did, however, issue a statement of policy outlining the conditions under which we would be willing to grant extensions of the effective date for individual substances. Under that policy, we have granted over 3,040 such extensions and still have a few more to go. Since then, however, we have tried our best to point out to all concerned that the extension was only the first hurdle and that this was only a temporary solution to the problem. The law contains no provision for administrative action to extend its effective date beyond March 6, 1961, and it is thus incumbent upon all concerned to see to it that appropriate petitions for regulations reach us in good season so that, where needed, regulations can be issued prior to the March, 1961 date.

Basic Philosophies in Administering Act

In our administration of the Act, we have some basic philosophies which must be considered in all cases. Some of these are:

(1) In any evaluation of a food additive, we must have clear-cut evidence of safety; there is to be no cutting of corners in this field. This is not to say that we propose to stand on ceremony; neither do we want to see anyone do any pharmacological work which is not necessary. We have urged all who have problems which appear to need pharmacological studies for their solution to discuss planned work with our Division of Pharmacology before starting it. While sometimes our people conclude that the program is not sufficiently comprehensive, there are other cases where our pharmacologists have been able to conclude that the work planned is not at all necessary. I believe it is in order to point out that just because a pharmacological study demonstrates that a proposed additive is quite innocuous does not mean that the work which was performed was unnecessary. How did we know until we got the facts?

(2) In the matter of whether or not a substance is GRAS, we have had a great deal of difficulty in explaining that just because a manufacturer and the FDA are agreed that a substance is safe, we do not have a basis for classing it as GRAS. We must be satisfied that scientists generally who are expected to know about the substance do actually have information and believe in its safety.

(3) In the matter of prior sanctions, we have held that the conditions under which they were granted are the only ones which may be considered in determining whether a specific product for a specific usage has a prior sanction. It has developed that in a number of cases, firms have changed their products somewhat and changed the conditions of use since a sanction was originally granted. Our position in such instances is that the new product does not have a prior sanction and unless it is GRAS, it is a food additive requiring a regulation.

(4) Our original concept of a food-additive regulation was that this would specify the substance, state the purpose of its use and limit the amount which would be present in the food, and that we would, in every case, have a good method of determining whether the limitation had been met through examination of the finished food product in the laboratory. In the case of many direct additives, this policy remains just as good now as it was when we formulated it. We did find, however, that in some cases—even involving direct additives—limitations were not necessary; and in those cases we were able to conclude that the method of analysis of the finished foods need not be as specific as would be necessary where a tolerance limitation had been set. When we came to the packaging field, we were faced with the problem where it was just impossible to anticipate the development of methods of analysis which would enable us to examine food products and determine how much of the packaging material had migrated. This, of course, could be demonstrated quite clearly in experimental work in the laboratory, but this was not possible in the case of commercial shipments.

We therefore announced our willingness to consider other approaches, and the first successful outcome of this was the polypropylene regulation which we issued several months ago. There we have our regulatory control based on the requirement that the resin itself meets certain specifications. We expect that this approach will work out satisfactorily in the development of other packaging material regulations.

(5) Also in the packaging field, our first concept was a consideration of the food-additive status of each substance used in making a product such as paper, for example. This would work out on the basis that if the specific substance migrated to the food, we would then have a regulation for that specific substance. When you look at the extension list that we published on March 1, 1960, covering substances used in paper packaging, it will, I believe, be quite apparent that approaching the problem on that basis would result in a monumental and perhaps never-ending job. Therefore, our people have been discussing with industry representatives the possibility of some sort of blanket regulation for specific types of packaging materials which will list the various components which themselves may be food additives and which may be used provided the packaging material meets certain extraction tests of an exaggerated character using various solvent materials. We haven't proceeded far enough on this type of proposal to enable me to give you a final comment as to whether it will work, but at the moment it looks quite promising. If it works for paper, why shouldn't it work for various plastic substances, cotton bags, and rubber equipment items?

These foregoing decisions, conclusions and evolutions of principle were not arrived at by formula or without a great deal of consideration, and many people have been involved. Many have contributed in an outstanding fashion to the progress that has been made, if progress it be. There have been some contributors or contributing factors which I am sure are entitled to credit for good intentions but which have not, in my view, constituted contributions of a helpful character.

Reporting by Trade Publications

Many of the trade publications have devoted excellent reporting and writing to the food-additives subject, and have undoubtedly been of tremendous help to their readers and to the Food and Drug Administration in their painstaking dealings with this active and live subject. Not all of the publications and the published material that I have seen which were intended for consumption and instruction of those whose business requires compliance with the amendment have, in my judgment, had the doubtless intended effect.

Some articles have tended to paint a picture of a problem of compliance with the amendment in such doleful terms as to carry the

conviction that compliance is impossible, and leave the view that there is simply no way to get from there to here. To the extent that this built up the view that the amendment is something that industry simply cannot live with, it produced unjustified alarm and discouraged constructive effort and development toward appropriate steps to get in line for compliance. If a thing cannot be done, there is no sense in trying. I think this attitude by some of the trade press pieces has pretty well disappeared, perhaps having been washed out by more intelligent application of the facts to the situation.

Of course, most of the trade advisors, counselors and representatives, including counselors-at-law who specialize in the food and drug field, have been extremely helpful to industry and to the Food and Drug Administration in interpreting, translating and explaining one to the other. In most instances, I am sure the explanations and interpretations have been accurate. In no instance do I intend to impugn the intent of anyone in attempting to explain interpretations or requirements.

Cranberry Episode

One of the episodes that occurred during the developmental stages of the evolution of the interpretations of the food-additives amendment was the so-called cranberry episode. I doubt that any single event produced more confusion, dissension and misunderstanding than this matter—which in truth and fact is not to be regarded as a food-additive episode.

Indeed, while I yield to no man in my admiration, esteem and affection for the distinguished chairman of this division of the Section on Corporation Banking and Business Law, and have had many pleasurable occasions wherein I could applaud his acumen, I do propose to take advantage of the moment to comment upon his piece in the January, 1960 issue of *The Business Lawyer*. I am sure that he will forgive me, since I know he shares my passion for accuracy.

His paper, entitled "The Cranberry Incident—Statutory Basis for the Administration Action Taken," has no doubt come to the attention of all of you. I say with all sincerity that it is a learned and concise discussion on the interrelationship and separate responsibility between the Department of Agriculture and the Department of Health, Education, and Welfare, and it shows a thorough and comprehensive

understanding of the Miller Pesticide Amendment; but it, I think, confuses some of the facts and some of the aspects of the so-called cranberry incident. It indicates that the Delaney cancer clause of the food-additives amendment of 1958 is philosophically and retroactively applied in the enforcement of the Miller Pesticide Amendment of 1958. It suggests that the absence of a Delaney cancer clause or similar language in the Miller Pesticide Amendment, and the retroactive application of such language drawn from the latter amendment, has the effect of resurrecting and breathing vigorous life into the per se doctrine which had, in the minds of those concerned with the legislation, been laid to its well-deserved rest by the enactment of the Miller and the food-additives amendments.

It concedes that the resurrection of the moribund and defunct per se doctrine narrows the resurrected and repealed doctrine, but that such narrowing does not, certainly under the circumstances, soften the vitality and effect of the resurrection.

The point in which I think my friend errs is that the enforcement pattern followed in dealing with the cranberry situation was not dependent upon or derived from any Delaney or other cancer clause, directly or indirectly. There was not a transplanting of a 1958 amendment to a 1954 law, nor any application of a previously nonexistent per se doctrine in the pesticide amendment.

Aminotriazole, the weed killer of the cranberry incident, is a poisonous and deleterious pesticidal chemical which may not be used on food crops in such manner as to leave residues except consistent with the promulgations of both the Department of Agriculture and the Department of Health, Education, and Welfare. Aminotriazole was used other than in accord with the no-residue basis of the Department of Agriculture and in the face of a no-tolerance position of the Food and Drug Administration. The facts were that appropriate investigational pharmacological work had shown the substance to produce cancer in experimental animals. Whether or not there was a Delaney amendment and we had been called upon to establish a safe level for aminotriazole as an ingredient in food, it would have been necessary for us to determine how much of a cancer-producing substance can safely be allowed in food. Since scientists do not know the answer to this question, and have not devised a scientific method of determining it for cancer in man, we would be powerless to determine a safe amount—whatever might be the words in the law.

We do not find ourselves able to agree with the suggestion in the piece that "the per se doctrine remains more firmly implanted than ever in the area of substances which under grossly exaggerated conditions deliberately introduced in order to induce injury to the test animal for the reasons indicated, are found to produce cancer. These are banned from foods even though no injuries of any nature are shown at lower levels of feeding." These substances are banned from foods because they must be either banned or permitted if they are to be used at all; and in order to be permitted, there must be a determination that such permission is a safe thing to grant. This is to say that whatever quantity will be consumed will not adversely affect the consumer.

Of course, however expert lawyers may become—and indeed we all immodestly agree that we may become amazingly expert for the period of a case—these are not subjects which can be decided by lawyers. Until pharamacologists and pathologists can tell us with knowledge the quantitative relationship between the ingestion of substances known to produce cancer and the likelihood of its producing cancer under a given set of circumstances, statements such as "No injuries of any nature are shown at lower levels of feeding" have little application.

When scientists can advise administrators as to what are safe tolerances for cancer-producing substances in human food, we will be the first, or certainly in the vanguard, of those who ask the Congress to permit us to do so. Wherever we are charged with the duty of saying yes or no with regard to the inclusion or omission of a substance in food when that yes or no depends upon an assurance that it is safe, we must have assurance. I am sure that no one argues really that we should indulge in the guess, however educated.

Lack of Cooperation in Some Areas

In some areas, we encountered a lack of willingness of manufacturers to give us full information as to just what they were doing. I think perhaps this arose largely out of the fact that we are dealing with people who had no previous contact with the Food and Drug Administration. They are, however, now getting to know us; and I hope that they realize we are only interested in the facts with a view to equitable enforcement of the statute.

There was a certain lack of willingness on the part of some firms with common problems to get together to try to solve these expeditiously. We understand that some of this reluctance has stemmed from fears that cooperation along these lines may involve some difficulties under the antitrust laws. We, of course, do not pretend to be experts in the antitrust field, but we are anxious to see these problems solved in the most expeditious way possible.

Last winter we did have quite a time because many people seemed to expect that the Congress would enact legislation to automatically extend this law (some wanted it extended with perhaps no closing date), but this was not forthcoming. We opposed this in the light of the administrative provisions for extension. Already we have been asked what our position is going to be if it appears early next year that some people will need more time to comply with the provisions of the food-additives amendment. Certainly, no policy on this question has been formulated by this Department. My own feeling is that those who have food-additive problems and have just sat back and done nothing are entitled to no consideration at all from the standpoint of extensions. I do, however, believe that there may be a sound basis for legislation authorizing further extensions where long-term pharmacological studies are underway and obviously cannot be completed before next March 6. In such cases, I would think that the possibility of further extensions—where it can be demonstrated that no undue hazard to the public health would result—may be well justified.

Of course, I am sure you are all aware of the debates which have been held about the Delaney, or anticancer, clause. I think there are many who expected that when the color-additives amendment was enacted, there would at the same time be a marked weakening of the provisions of the Delaney clause in the food-additives amendment.

I can't tell you that we have solved all our problems in this food-additives field. We still have them; and we invite all the help we can get to assist us in solving them for the benefit of all concerned: consumers, manufacturers and distributors. I think if we all realize that this is a good law which will, in the long run, benefit all of these groups, we can work better to achieve its objectives.

I had hoped to be able to discuss in some detail progress in the field of color additives in the light of the color-additives amendment, which became law last month. All I can tell you, however, is that we are working diligently in the matter of regulations and should have something to present for consideration reasonably soon. **[The End]**

Safe Food Additives and Additives Generally Recognized as Safe—There Is a Difference

By WILLIAM W. GOODRICH

Mr. Goodrich Is Assistant General Counsel for Food and Drugs, Department of Health, Education, and Welfare. This Paper Was Read Before the Meeting of the Division of Food, Drug and Cosmetic Law, Section of Corporation, Banking and Business Law, American Bar Association, August 31, Washington, D. C.

ON MARCH 6, 1961, the enforcement provisions of the food-additives amendment of 1958 become fully effective. Food additives that have not been proved safe will then become food adulterants.

Before next March, the food and chemical industries must complete the tremendous task of gathering and presenting sound scientific data to support the needed food-additive regulations. And the FDA must shoulder its responsibility for reviewing this data and issuing regulations under which food additives can be safely used.

Most of our efforts thus far have been devoted to the immediate problems of the transitional period; the problems coverage of the amendment, of exemption and of obtaining time extensions. This transitional period is near the end, so we need not be seriously concerned with the existing extensions. They are important only as they provide advance notice of the magnitude of the job that remains to be done.

But the basic questions of coverage and of exemption will grow in importance as we approach the effective date of the legislation. Since a great amount of energy is being exerted to have substances included on the so-called GRAS list, and since valuable time is being lost in obtaining action on food-additive petitions for some substances

that cannot be cleared ultimately under this exemption, we welcomed the opportunity to review this problem as a part of today's program.

Any substance which is generally recognized among appropriately qualified experts as an article which has been adequately shown to be safe for its intended use is not a "food additive." There is no need to prove such an article safe, when its safety is generally recognized. General recognition of safety may be based upon reported scientific studies; and in case of substances used in food prior to January 1, 1958, it may be based on common experience with the article as an item of food.

The concept of general recognition of safety is an old one with us. It originated in the new-drug provisions of the 1938 Act. The idea was carried forward in the pesticide chemicals amendment of 1954, and it was improved and made a part of the food-additives amendment of 1958. In explaining the clause to the House Committee on Interstate and Foreign Commerce, Mr. Larrick said that it was designed to exclude from the new requirements for proof-of-safety "those substances which, according to the general consensus of the competent scientific opinion, are safe under the conditions of their intended use." Mr. Larrick conceded that the concept of scientific consensus cannot be reduced to the precision of a mathematical formula, but he said that experience with new drugs convinced us that it was a workable idea.

Basic Part of Exemption

As I review what has been written and said on this subject, particularly in the last year, I am not sure that people outside the Department fully understand what, to us, is a very basic part of this exemption. A substance may be a very safe one, but not recognized as such simply because little or nothing is known about it in the scientific community. A safe substance may lack general recognition because it has been guarded as a trade secret. A safe substance may lack general recognition because only negative results have been obtained in experimentation, none of which warranted publication.

There has been a tendency to confuse general recognition of safety with the manufacturer's well-founded conviction that his additive is in fact safe. But there is a difference between a product generally recognized as safe and one which can be proved safe by assembling all the scientific data about it. The first is exempt. The latter is not.

Not too long ago, an attorney from a very responsible chemical firm called me in a state of utter exasperation. He had an important product, used in a variety of foods, which he knew was safe. He had collected scientific data to prove this. He had presented the material to Dr. Lehman, and Dr. Lehman agreed with him that the mass of scientific information he had gotten together would be adequate to prove the substance to be safe. He simply could not understand why we refused to put this article on the so-called GRAS list. This informal clearance, it seemed to him, was all that should be required. The steps necessary to file a petition and obtain a regulation were looked upon as the paper shuffling of bureaucracy.

It seemed very clear to me that if it was necessary to assemble a large volume of scientific data in order to convince a scientist as well informed as Dr. Lehman that the substance was safe for its intended use, it could by no means be classed as generally recognized as safe by the scientific consensus. And since the old informal clearances which preceded the food-additives amendment no longer may be issued, the food additive could attain lawful status only through the petition and regulation process expressly prescribed by law.

When I explained all this to the attorney, he asked a very practical question: What difference could it make, so long as we were convinced that the product was safe, whether it was on the GRAS list or in a regulation providing for its safe use? My explanation was that to place the substance on the GRAS list not only could not be justified under the law, but it would remove the additive from the controls of the new law. It would be a decision on our part that no regulation is necessary to assure the additive's safe use.

GRAS List Is Advisory

The GRAS list is advisory only. If any substance listed were used contrary to the conditions specified in the GRAS list, the burden would be on the Department to prove in an enforcement case that it is not generally recognized among qualified experts as having been proved safe for such uses.

The soundest approach from the standpoint of public protection is to classify all substances about which there is any doubt whatsoever as "food additives" and not to exempt them from the law by listing them as GRAS.

This approach has judicial support in the only three cases we have had under this somewhat vague language. Two of the cases arose under the new-drug provisions of the Act and one under the food-additives amendment itself.

In *Merritt Corporation v. Folsom*, CCH FOOD DRUG COSMETIC LAW REPORTS ¶ 7462, 165 F. Supp. 418, the company sued to restrain the institution of multiple seizure actions against a drug known as "Clarimycin." Merritt alleged that this drug, a neomycin sulfate lotion for the treatment of acne, was generally recognized as safe, and thus not a new drug, but that the Department was nonetheless engaged in a multiple seizure campaign against it, charging it to be a new drug for which no application had become effective.

Merritt presented medical affidavits which asserted that topical neomycin sulfate is generally recognized as safe in the treatment of acne, even when used over prolonged periods of time. The government's medical affidavits denied this. They specifically called attention to the possibility, only recently been reported in the medical literature, that long-term use of this antibiotic lotion would cause sensitization to neomycin and cross-sensitization to streptomycin. The affidavits also asserted that the long-term use of neomycin in the treatment of acne was new and had not become generally recognized as safe.

On the conflicting affidavits the government moved for summary judgment of dismissal. The court sustained the motion, holding that where there is a genuine difference of medical opinion among experts whether a drug is generally recognized as safe for the treatment of a particular disease, it must be concluded that the drug is not *generally* recognized as safe in the treatment of that disease.

This case was decided in May of 1958, and it was followed in 1959 in a similar decision by the United States District Court for the District of New Jersey in *U. S. v. "Trim Reducing-Aid Cigarettes,"* 178 F. Supp. 847. In the *Trim Cigarettes* case, the government filed a libel charging that the cigarettes, containing combustible tartaric acid and recommended for weight reduction, were a new drug because not generally recognized as safe. Cross motions for summary judgment were filed on conflicting affidavits, and the district court found that the article was indeed a new drug. Judge Wortendyke recognized in the supporting affidavits a direct contrariety of medical and scientific opinion on the question whether the use of combustible tartaric acid in a cigarette for reducing body weight is generally recognized as safe.

Assuming that all of the deponents were duly qualified to have an opinion on the safety question, he held that this difference of opinion itself would establish that the drug could not have the general recognition of safety required to take it outside the statutory definition of a new drug.

The food-additive case was decided by the District Court for the District of Columbia without a written opinion. Los Angeles Smoking and Curing Company sued, seeking a declaratory judgment that sodium nitrate and sodium nitrite used in the curing of fish in a level of no more than 200 ppm was not a "food additive," because these substances were generally recognized among appropriately qualified scientific experts as substances which have been adequately shown to be safe, both through scientific procedures and through long use in curing fish. Again, a scientific conflict appeared in the affidavits filed by both sides to support motions for summary judgment. Summary judgment of dismissal was granted on the government's motion.

Judge Youngdahl refused to resolve the jurisdictional question whether nitrates and nitrites are generally recognized as safe. He was impressed by the fact that he was being asked to decide a serious issue of safety, when the whole plan of the food-additives amendment called for an initial administrative decision by scientists and for review of safety decisions in the United States Courts of Appeals. He held that the petitioner would have to file a food-additive petition. In it, the firm could attempt to show not only that nitrates and nitrites are safe in curing the fish, but also that they are so generally recognized among qualified scientific people as having been proved safe for this use that they are exempt from the statute. In effect, this holding was that the jurisdictional argument that a substance is not a food additive can be supported by scientific data in the food-additive petition, that the Department can be called upon to make a decision on the jurisdictional issue when it acts on the petition, and that if that decision is adverse, the petitioner's remedy would be by judicial review in the court of appeals.

Proving Article Is GRAS

These cases, we believe, teach us how to prove that a substance is *not* one that is generally recognized as safe. But the question that gives us immediate concern is how to prove that an article is GRAS.

Our first efforts here were to poll the scientific community on a large number of substances which we thought could qualify as GRAS. This was done by sending the proposed lists to approximately 800 scientists, representing a variety of disciplines, to solicit their views. In addition, the lists were published in the *Federal Register* with an invitation for anyone else who might have an opinion to offer it.

Some scientists apparently felt slighted that they were not among the 800, and others felt that some of the 800 should not have been selected. In any event, the word got around that the select 800 would have the last word and that that word might not be a reliable one. Most of the suggestions made about the procedure were that a smaller group of especially informed scientists should be selected for advice. And, it was said, the choice should be made from scientists who had studied the particular additive or additives in question.

While we can readily agree that all the 800 were not qualified to evaluate the safety of each of the substances on the initial list, they did represent a good cross section of the scientific community. All the opinions expressed to us were thoughtfully weighed before reaching the ultimate decision on the list. Plainly mistaken or ill-advised opinions were thrown out. But the very scope of the initial list required that widely diversified views be sought.

Folic Acid in Dietary Food Supplements

Since the publication of the initial list, we have had two experiences with food additives which called for the views of smaller groups on the general-recognition-of-safety question. The most recent was on the status of folic acid in dietary food supplements. Folic acid became an ingredient of food supplement vitamin preparations about 1946. By early 1959, several reports had appeared in the medical literature to the effect that folic acid had the capacity of masking the blood symptoms of pernicious anemia, while allowing the accompanying nervous system changes to progress. This created a hazard to a small group of individuals with undiagnosed, untreated, pernicious anemia.

In November, 1959, when a GRAS list was under consideration in the Department, we concluded on medical advice that the vitamin was not generally recognized as safe for use in vitamin supplements. In early 1950, in response to a letter inquiry, the FDA expressed the opinion that folic acid at levels not exceeding 0.4 milligrams per day

would be generally recognized as safe for use in vitamin food supplements. But folic acid was not placed on the GRAS list.

In June, 1960, the FDA consulted a group of outstanding hematologists and internists who specialized in blood disorders on whether any level of folic acid in vitamin preparations for over-the-counter sale could be regarded as generally recognized as safe. Later in June, a broader group—including experts in general medicine, preventive medicine, nutrition, hematology, pediatrics and obstetrics—was consulted. It was plain from the opinions offered that no level of folic acid in vitamin supplements is generally recognized as having been adequately shown to be safe. Folic acid, at levels 0.4 milligrams and below in vitamin preparations, was given a food-additive extension until next March to allow time for firms that wish to promote it for sale to the public without prescription to present evidence of its safety through the food-additive procedures.

Arsenic Preparations in Medicated Animal Feeds

Our other experience involves arsenic preparations in medicated animal feeds. Two of the inorganic arsenicals have long been known to be carcinogenic. Before the organic arsenicals can be approved under the food-additives amendment, their carcinogenic potential will have to be studied. This is because of their relationship to the inorganic arsenicals. But if the preparations are generally recognized as having been shown safe for animal feed use, they are exempt and no food-additive clearance will be required.

The FDA made a suggestion to the food manufacturers as to how they might proceed to establish general recognition of safety. The suggestion was that experts selected from a group of well-qualified scientists in the field of environmental cancer be surveyed for their views. This has not yet been done. The plan offered was, in our view, the right way to obtain a reliable opinion on the question.

It seems clear that persons convinced that their products are generally recognized as safe, but who have not been able to convince us, would be well advised to start to work on food-additive petitions. If the substances are as safe as the petitioners think they are, there should be little trouble preparing convincing petitions. And we can anticipate early issuance of the needed regulations. Extending the argument over the GRAS list is not likely to be profitable.

[The End]

By KENNETH E. MULFORD

The Effect of the Food-Additives Amendment on Ing

ONE OF THE UNINTENTIONAL BY-PRODUCTS of the food-additives amendment of 1958 is that we shall always have problems to talk about at gatherings like these. I suspect that the 1958 Act promises a bright future for those of us in the legal profession.

I speak here today primarily about ingredients that are added to foods intentionally in order to accomplish a beneficial effect. The principal impact of the law on intentional ingredient suppliers has been in terms of the time and effort spent on substances that were in use prior to January, 1958, without undue risk to health.

Are these old ingredients generally recognized as safe (GRAS) or are they sanctioned? If they are not, have or will extensions be obtained? Are data available for filing a petition? If not, is the cost of developing such data justified; and where and how can the data be obtained in time to meet the March deadline?

It is such questions as these that the ingredient supplier must answer, and, in so doing, increases the work load in almost all phases of his business. Operating personnel must obtain information from their material suppliers about the status of raw materials, packaging, etc., under the new law. The sales force, in turn, must make the same type of explanation to their customers. Lawyers, of course, are heavily involved in giving advice as well as in handling formal proceedings before the Food and Drug Administration.

One problem upon which there has been considerable disagreement from the legal viewpoint involves the FDA procedures used for GRAS listing. While FDA representatives have repeatedly indicated that many materials may be GRAS even though they have not been subject to the FDA listing procedure, and further that industry may reach a conclusion at its own risk as to whether ingredients

on Ingredient Suppliers

This Paper Was Delivered at a Symposium on the Food-Additives Amendment to the Division of Food, Drug and Cosmetic Law of the American Bar Association at Its 1960 Meeting. The Author Is Chairman of the Food Additives Committee of the Manufacturing Chemists' Association.

are GRAS, the fact remains that the supplier finds considerable customer dissatisfaction if there is no FDA ruling.

I believe I am correct in saying that most members of the Food, Drug, and Cosmetic Division do not share the view that GRAS listing by FDA should expose the ingredient to the casual and apparently confidential opinions of scientists who have had no particular experience with or knowledge of the product. For reasons stated in the paper by Joseph D. Becker in the July issue of the FOOD DRUG COSMETIC LAW JOURNAL, the scientists qualified to evaluate the safety of a particular ingredient are the ones who have made a thorough study of its uses and physiological properties, and not a large group of what might be called "outer space" scientists with no particular knowledge of the ingredient. Moreover, failure to make the replies from the scientists available for inspection leaves those interested in the product with no practical opportunity to comment and sometimes subject to unpleasant surprises in the final listing.

Another most difficult problem arises in developing a practicable, quantitative method of analysis for some additives in or on food under Section 409 of the Act. The increased work load on operating, sales and administrative personnel can generally be absorbed without too much difficulty. And, of course, there are always plenty of lawyers around willing to give advice.

But this is not the case when it comes to the research necessary to develop analytical methods, because there are only so many research

workers and facilities available. Moreover, at the time the law was enacted, the research workers and their facilities were generally scheduled to capacity.

It would be difficult to overemphasize the seriousness of this problem. The chemistry of foods, as you know, is very complex. As a result, an analytical method that is satisfactory for ingredient X in one food may be entirely useless for determining the amount of the same ingredient in another food. A method that is practicable for a food with a long shelf life may not be practicable for a food such as milk that is quickly consumed. Also, FDA is requiring a petitioner to supply validation data showing the operability of the method and its degree of accuracy.

Some people have contended that the new law would result in a diminution of the amount of research and development in the field of food ingredients. It is a matter of real concern that the time-consuming work on old or existing ingredients, as a practical matter, has almost excluded work on new products. The extent to which the development of new products may be renewed after the regulations are completed on old ingredients remains to be seen, and will undoubtedly depend upon the successful and reasonable application of the law to existing substances.

Development of Short-Term Tests

In any event, the decision which management must make on whether to spend or not to spend research money on new food ingredients is most difficult. One of the scientific problems that must be faced is the development of short-term tests that will assure safety adequately enough to enable a manufacturer to measure consumer acceptance of a new-food ingredient. In many cases no prudent management could be expected to incur the expense of the full-scale safety evaluation recommended by the Food Protection Committee of the National Research Council without commercial tests for acceptability.

It will be recalled that the committee, in its "Principles and Procedures for Evaluating the Safety of Food Additives," stated that:

> Long-term feeding is conducted on the premise that the effects of the lifetime ingestion of an additive in food by man cannot be predicted from results of experiments less stringent than lifetime feeding in a short lived mammal . . . .

It would then seem to follow logically that safety for one month's production of finished food, corresponding to about 1/840th of the lifetime ingestion, could be established on a different, less time-consuming basis. Many industry comments on the regulations under the food amendment requested inclusion of a provision for experimental trials—provided, of course, that the trials were safe—but no such provision was included in the FDA regulations.

Additional Problems to Be Faced

Suppliers may face additional problems under the recently enacted color-additive amendments of 1960 even though they produce noncoloring ingredients. Considerable concern arises over the statement in the definition that substances "capable" of imparting color are subject to the amendments except those which the Secretary determines by regulation are used solely for noncoloring purposes. Since practically every substance is "capable" of imparting color, this would appear to mean that all food ingredients, other than pesticide residues which carry a specific exemption, are subject to regulation stating they are used only for noncoloring.

In a letter to the House Committee on Interstate and Foreign Commerce, Secretary Flemming made the following statement on the bill's coverage:

> Additionally, it is our view that the bill is intended to regulate substances that color or are capable of coloring to a degree apparent to the naked eye.

It would appear to be appropriate, therefore, to include in the general regulations under the color-additive amendments a statement that the definition does not include food ingredients which in their actual use do not color the food to a degree apparent to the naked eye.

While such a general regulation will not solve all of the problems foreseen under this definition, it would reduce the number of regulations for exemption of individual products under the new color law.

Clearance of Old Ingredients Under Amendment

However, the most pressing problem, from industry's standpoint, involves the clearance of old ingredients under the food-additives amendment. It is now apparent that there will be many uses for these products that will not be cleared by the final deadline of March

5, 1961—even though no public hazard is involved—because of the time inherently consumed in the petition procedure.

I recently calculated the time involved in processing petitions on two related products on which a food-additive regulation was issued not so long ago. It took over 500 days from the time of filing until the issuance of the regulation—the time during which the petitioner awaited action by FDA was 372 days, while the time during which FDA had to await action by the petitioner on requests for further data was 137 days. The petitions, incidentally, involved products on which FDA had been given extensive data on composition and safety testing before passage of the 1958 Act.

All of this is said, not in criticism of the FDA or the petitioner, but to underscore the seriousness of the time problem faced by industry in meeting next year's deadline.

The color amendments point the way to a simple solution. Under this law the closing date on the provisional listing or use of a color additive is open-ended, in the sense that the Secretary may postpone the closing date "if such action is consistent with the objective of carrying to completion in good faith" the necessary scientific investigation.

Author's Recommendation

I personally would urge that the food-additives amendment be changed so that the Secretary will have similar latitude in handling old additives or those in use before January, 1958. Specifically, I recommend that the effective-dates provision be amended by deleting the "not later than two years" clause and substituting a provision that the Secretary may prescribe an additional period or periods if he finds that the extension involves no undue risk to public health, that a regulation under Section 409 has been or is to be proposed with respect to the food use, and that scientific investigations have been or are being brought to completion in good faith to obtain the necessary data for issuance of a regulation under Section 409.

This change would entail no compromise with the principle of public safety, for obviously the Secretary would have, as at present, full discretion to determine if any undue risk were involved. But it would go a long way towards facing the facts of life in scientific research. **[The End]**

Are Empty Containers Food?

By JOHN G. KUNIHOLM

This Paper Was Read at the Eighty-Third Annual Meeting of the American Bar Association's Section of Corporation, Banking and Business Law, Division of Food, Drug and Cosmetic Law, August 31, 1960. The Author Is Attorney, Hercules Powder Company, Wilmington, Delaware.

THE IMPOSITION of predistribution controls over chemical additions to food cast more darkness than light on the legal status of containers that contribute trace residues to packaged food. Yet, it is clear that the presence of an unapproved container-residue in food is in plain violation of the food-additives amendment.[1] Unquestionably then, the entire package, including the food and its container, is subject to the full range of enforcement powers possessed by the Food and Drug Administration.

More doubtful, however, is the scope of the Food and Drug Administration's control over empty containers. Five years ago, the possible inclusion of tin cans and cardboard boxes within the statutory term "food" would have appeared absurd. However, as a result of recent trends in legislative draftsmanship, a literal reading of a statute quite often brings about entirely unexpected results. In the food and chemical field this tendency to all-inclusive jurisdictional phraseology is also displayed in certain portions of the color-additive amendments [2] and the Federal Hazardous Substances Labeling Act.[3]

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[1] Food-additives amendment of 1958, 72 Stat. 1784, 21 USCA Secs. 321, 331, 341, 342, 346, 348 (1959).

[2] Color-additive amendments of 1960, 74 Stat. 397, *e. g.*, Sec. 101(c): "The term 'color additive' means a material which . . . (A) is a . . . substance, . . . and (B) when added or applied to a food, drug, or cosmetic, or to the human body or any part thereof, is capable . . . of imparting color thereto."

[3] Federal Hazardous Substances Labeling Act, 74 Stat. 372 (1960), *e. g.*, Sec. 2(f): "The term 'hazardous substance' means:

"1. (A) Any substance or mixture of substances which (i) is toxic, (ii) is corrosive, (iii) is an irritant, (iv) is a strong sensitizer, (v) is flammable, or (vi) generates pressure through decomposition, heat, or other means, if such

(Continued on following page)

One cannot escape the fact that a literal reading of the food-additives amendment brings all empty containers within the reach of its provisions.[4] Indeed it appears that containers and the ingredients used to make them are subject to the full range of regulatory controls that the Food and Drug Administration now exerts over foods.[5]

However, are empty containers really foods within the intent of this law? Is Food and Drug empowered to seize shipments of empty containers? Notwithstanding the unqualified breadth of the statutory language, the legislative history indicates that such a result was neither foreseen nor intended by Congress.

The FDA's authority to proceed against shipments of food bearing unsafe packaging residues in violation of Section 402(a)(2)(C)[6] is clear and undisputed. Less clear, however, is its authority to reach behind the food manufacturer and proceed against shipments of empty food containers moving from the container manufacturer to the food

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(Footnote 3 continued)
substance or mixture of substances may cause substantial personal injury or substantial illness during or as a proximate result of any customary or reasonably foreseeable handling or use, including reasonably foreseeable ingestion by children.

"(B) Any substances which the Secretary by regulation finds, pursuant to the provisions of section 3(a), meet the requirements of subparagraph 1(A) of this paragraph."

[4] Sec. 201(s) defines the term "food additive" as "any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food (including any substance intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food; and including any source of radiation intended for any such use). . . ." Several added exclusionary provisos then exclude substances whose safety has previously been determined.

[5] Sec. 201(s) encompasses substances "otherwise affecting the characteristics of any food" as well as those "becoming a component of food." Early fears that all containers, irrespective of the existence of migration, would be covered since packaging inevitably affects the characteristics of food, *e. g.*, by protecting it from contamination with filth, were put to rest by Senator Hill's remarks on the Senate floor prior to passage: "I would add that the term 'otherwise affecting the characteristics of any food' refers to an effect not generally recognized as safe . . . but innocuous effects of packaging, such as protection from dirt, retarding moisture loss, preserving shape, providing convenience in use, handling and storage, and the like, would not be covered." (104 *Congressional Record* 19359 (1958).) This distinction is reflected in the regulations: "If there is no migration of a packaging component from the package to the food, it does not become a component of the food and thus is not a food additive." (21 CFR, Sec. 121.1(e).)

[6] 52 Stat. 1046 (1938), as amended 68 Stat. 559 (1954); 72 Stat. 1784 (1958), 21 USC Sec. 342(a)(2)(C).

"Section 402. A food shall be deemed to be adulterated . . . (a) . . . (2) . . . (C) if it is, or it bears or contains, any food additive which is unsafe within the meaning of Section 409. . . ."

packer or, to go back even further, to reach shipments of packaging components moving from a supplier to a container manufacturer.

In answer to a question at the 1958 FDA-FLI conference, it was stated:

> We think that if a package intended for use as a food container contains a substance whose safety has not been established, it would be subject to action *when in the jurisdiction of the Federal Law.*[7] (Italics supplied.)

When is a container "in the jurisdiction of the Federal Law"? The FDA apparently believes that it is not necessary to find the offending residue actually in the food before action can be taken, for at the same conference the spokesman added:

> With an additive not generally recognized as safe, it would be our purpose to take action that would restrict the use of the packaging material rather than wait until large quantities of food have been damaged by it.[8]

The FDA has expressed an intention to undertake seizure at the point where the containers are being filled with food.[9] Undoubtedly such enforcement action would be bottomed on the "doing of any other act" language of Section 301(k),[10] that is, the act of filling the container is an act done while the food is "held for sale after shipment in interstate commerce" and results in the food "being adulterated" under Section 402(a)(2)(C) by reason of the transfer to it of uncleared packaging residue.

At the 1959 conference, the Food and Drug Administration was asked on what basis they would take action against the packaging manufacturer. The reply was:

> This could be done on either the theory that the manufacturer caused the food to be adulterated or the theory that the packaging itself is a food additive which is unsafe within the meaning of the law.[11]

The second theory appears doubtful since Section 301 limits FDA regulatory action to transactions involving food, and all food additives may not be foods. Section 201(f) defines "food" as follows:

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[7] 14 FOOD DRUG COSMETIC LAW JOURNAL 13 (1959).

[8] Article cited at footnote 7, at p. 59; *Accord* 15 FOOD DRUG COSMETIC LAW JOURNAL 232 (1960).

[9] 15 FOOD DRUG COSMETIC LAW JOURNAL 232 (1960).

[10] 52 Stat. 1042 (1938) as amended, 62 Stat. 582 (1948), 21 USC Sec. 331(k). The section prohibits "The alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the labeling of, or the doing of any other act with respect to, a food . . ., if such act is done while such article is held for sale (whether or not the first sale) after shipment in interstate commerce and results in such article being adulterated or misbranded."

[11] 15 FOOD DRUG COSMETIC LAW JOURNAL 234 (1960).

The term "food" means (1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article.[12]

Although it is clear that clause (3) brings all deliberate food additives within the scope of the statutory term "food," there is less basis for the view that inert packaging residues are "used for components of" food. Indeed, the prior drafts of the food-additives amendment specifically added a fourth clause to Section 201(f) bringing all food additives within the term "food." [13] In a statement presented to the House committee,[14] the FDA explained that the language deeming packaging residues to be "food" was required to make it clear that any food additive was subject to regulatory action from the moment it entered interstate commerce. After pointing out that the third clause in Section 201(f) brought all deliberate food additives under the statutory term "food," the statement noted:

It is not so clear, however, whether a substance which is not intended to be "used for a component" of food but which, as in the case of a migratory component of food packaging material, may be [*sic*] reason of its use foreseeably find its way into food, is itself "food" within the meaning of Section 201(f)(3) of the present act.[15]

Congress failed to include the fourth clause in the bill as finally enacted.[16] In explanation, it was noted that the language was surplusage—not because Section 201(f)(3) already covered incidental additives but because packaging residues were sufficiently dealt with as food additives. Congressman John Bell Williams explained on the House floor:

Another question I have been asked is why H. R. 13254 does not contain a provision of the type in H. R. 6747 which brought "food additive" within the meaning of the term "food."

It was the feeling of the Committee that such a provision would be surplusage since the present Food and Drug Law, in Section 201(f), already defines "food" as including all components thereof. Since substances which get into food incidentally in its manufacture, handling, or packaging would be dealt with as a "food additive" under the bill, there appears to be no need to have such substance also defined as a "food." [17]

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[12] 52 Stat. 1040 (1938), 21 USC Sec. 321(f).

[13] H. R. 6747, 85th Cong., 1st Sess., Sec. 3 (1957): "The term 'food' means (1) articles used for food or drink for man or other animals, (2) chewing gum, (3) articles used for components of any such article, and (4) chemical additives."

[14] Hearings before a Subcommittee of the Committee on Interstate and Foreign Commerce, House of Representatives, 85th Cong., 2d Sess. (1958), p. 455.

[15] Hearings cited at footnote 14, at p. 456.

[16] The bill which became law was H. R. 13254, 85th Cong., 2d Sess. (1958).

[17] 104 *Congressional Record* 17418 (1958).

There is substantial authority, then, for the view that a packaging residue is a food additive but not, as is the case with intentional additives, a food component within the language of Section 201(f)(3). Some support for this view has been expressed by the FDA.[18] They have stated publicly that they do not regard empty containers as foods [19] or empty cans subject to food labeling requirements,[20] and disavowed authority to seize empty containers prior to the time they reach a food processing plant.[21] Curiously, though, they have stated that a can manufacturing plant is subject to FDA inspection powers.[22]

It was noted earlier that the FDA has considered two theories under which enforcement action might be taken against the packaging manufacturer. If it be concluded that empty containers are not foods, we are left with the concept that the packaging manufacturer "caused" the food to be adulterated.

The "causing" theory is derived from the "prohibited acts" section of the law,[23] which is prefaced by the broad statement: "The following acts and the causing thereof are hereby prohibited."

Whether the FDA may prosecute shippers of packaging components or empty containers on the grounds they have "caused" the subsequent adulteration of food is beyond the scope of this article. However, it does seem clear that the FDA lacks authority to proceed on the theory that packaging is itself a food or food component; and if this be true, it means that shipments from a supplier of components to a packaging manufacturer, and from a packaging manufacturer to a food processor, are immune from seizure.

This result appears reasonable since it tends to focus enforcement on adulterated food rather than on empty food containers. **[The End]**

[18] 15 Food Drug Cosmetic Law Journal 232 (1960).
[19] Article cited at footnote 18.
[20] Article cited at footnote 18.
[21] Article cited at footnote 18.
[22] Article cited at footnote 18.
[23] 52 Stat. 1042 (1938), 21 USC Sec. 331.

FOOD ADDITIVES: Food P

By PAUL E. JOHNSON

THE FOOD PROTECTION COMMITTEE is a committee of the Food and Nutrition Board of the National Academy of Sciences-National Research Council. The academy was chartered by Congress and the charter approved by President Lincoln in 1863. The Council was established by the academy in 1916 at the request of President Wilson as an aid in organizing the scientific resources of the country. It was perpetuated by Wilson in an executive order in 1918. The duties of the council were outlined in that executive order, and were restated in Executive Order No. 10668, May 10, 1956.

They are, in brief, (a) to stimulate research in the sciences and in the application of the sciences to the useful arts, with the object of increasing knowledge, strengthening national defense and contributing in other ways to the national welfare; (b) to survey the possibilities of science, to formulate comprehensive research projects and to develop means of using scientific and technical resources of the country in these projects; (c) to promote cooperation in research at home and abroad, but to give encouragement to individual initiative; (d) to serve in bringing American and foreign investigators into cooperation with the military and civil branches of the government; (e) to direct the attention of investigators to the importance of military and industrial problems in connection with national defense, and to aid in solution of these problems; and (f) to gather and collate scientific and technical information.

The academy-research council is required by the terms of its charter to render advice on scientific matters to agencies of the federal government upon request. It is, however, not itself an agency of the government, and no funds are appropriated by Congress for its use.

The Food Protection Committee was organized in 1950 at the urging of interested industrial groups. The decision to establish the

od Protection Committee Activities

Mr. Johnson Is Executive Secretary, Food Protection Committee, National Academy of Sciences-National Research Council. This Paper Was Presented at the Nineteenth Annual Meeting of the Institute of Food Technologists, May, 1959, in Philadelphia.

committee was prompted by the rapid development of new pesticide chemicals and functional food additives after World War II and by the attention being given the use of chemicals in foods by legislative and control agencies.

The committee operates within the terms of reference indicated by the stated duties of the academy-research council. Its primary purposes have been (a) to serve as a fact-finding and advisory body for government and industry in the general field dealing with public health implications of the use of chemicals in foods; and (b) to foster cooperation between industry and government in assuring the safety and wholesomeness of the food supply.

The activities of the committee are financed by grants from business concerns. Representatives of the contributing concerns, trade associations, government agencies and scientific and technical societies make up a liaison panel upon which the committee depends to an important extent as a source of information and for guidance in formulating its program. Final judgments and conclusions are the responsibility solely of the committee, however, and public release of the findings of the committee is subject only to approval of the Food and Nutrition Board, the committee's parent organization in the academy-research council.

The first project of the committee was the preparation for public information of a general statement[1] concerning (a) the necessity

[1] *Use of Chemical Additives in Foods,* NAS-NRC Publication, December, 1951.

for use of pesticides and intentional chemical additives in assuring the food supply, maintaining quality and acceptability of foods, etc.; (b) the public health hazards associated with use of pesticides and intentional additives; and (c) the precautions taken by industry and government to assure safety of use of these materials. The statement was intended to be objective and reassuring.

This statement was followed by a report [2] which developed some general principles involved in estimating the safety for use in foods of additives and in evaluating hazards from use of pesticides. It also outlined some basic considerations in the development of a new pesticide for use in the production or storage of food. This report was later expanded into two reports. One [3] dealt with principles and procedures for estimating the safety of intentional additives and the other [4] with the development and use of pesticides.

The principles set forth and the general procedures proposed in these publications have been widely adopted. The 1952 report [5] influenced the shaping of some of the provisions of Public Law 518 (1954) which amended the Food and Drug Law in its provisions for control of pesticides in or on agricultural commodities. The 1954-1957 statement of principles and procedures for evaluating safety [6] has been the basis for important pronouncements from the Joint Expert Committee on Food Additives of the Food and Agricultural Organization and the World Health Organization. It, along with other statements of the academy-research council, is used as a guide by the Food and Drug Administration in reaching decisions on petitions for tolerances for additives. The principles and procedures outlined in this report are now being reviewed by the committee and a revision will probably be published soon.

These statements deal primarily with general toxicology and the estimation of hazard associated with the toxicity of chemicals used in food. The particular case of carcinogenicity is not treated in detail. The problem of carcinogenic hazard from use of food additives is being

[2] *Safe Use of Chemical Additives in Foods*, NAS-NRC Publication, December, 1952.

[3] *Principles and Procedures for Evaluating the Safety of Intentional Chemical Additives in Foods*, NAS-NRC Publication, November, 1954, reprinted January, 1957.

[4] *Safe Use of Pesticides in Food Production*, NAS-NRC Publication No. 470, November, 1956.

[5] Cited at footnote 2.

[6] Cited at footnote 3.

considered separately by a subcommittee of the committee. The group is attempting to formulate general principles and to suggest a practicable set of procedures for answering the question: How does one arrive at a conclusion that the carcinogenic hazard from use of an additive is insignificant in relation to the benefits to be derived from such use? This is the only practical approach available since there is no way of proving that a material is never carcinogenic for man. The report of this subcommittee has not yet been prepared for public release.

The committee has prepared a few reports which review the available data on toxicology and safety of individual food additives or classes of additives [7] and is presently reviewing information concerning the glycerides of lauric acid. The committee does not consider such activity as a particularly productive one but has engaged in it to a limited extent, primarily at the specific request of industry and government.

An activity adopted by the committee early in its existence was the compilation of information of use to industry and public agencies concerned with the safety and wholesomeness of food. Three major projects of this kind have been completed. The first [8] was the compilation of an annotated bibliography of analytical methods for pesticides which filled a need at the time. Of more lasting interest are the other two projects.

Since the investigation into the use of chemicals in foods made by a select committee of the House of Representatives of the Eighty-first Congress (the Delaney committee), there have been repeated statements to the effect that hundreds or thousands of untested, probably poisonous chemicals are used in foods. The discussions indicated a lack of any precise public knowledge about either the number or nature of the additives used. In an attempt to remedy this lack of knowledge, the Food Protection Committee compiled a list of intentional additives actually in use. The compilation [9] was published in

[7] *The Safety of Mono- and Diglycerides for Use as Intentional Additives in Foods*, NAS-NRC Publication No. 251, December, 1952. *The Safety of Polyoxyethylene Stearates for Use as Intentional Additives in Foods*, NAS-NRC Publication No. 280, August, 1953. *The Safety of Artificial Sweeteners for Use in Foods*, NAS-NRC Publication No. 386, August, 1955. *The Relation of Surface Activity to the Safety of Surface Active Agents in Foods*, NAS-NRC Publication No. 463, October, 1956. *The Safety of Polyoxyethylene (8) Stearate for Use in Foods*, NAS-NRC Publication No. 646, December, 1958.

[8] *Annotated Bibliography of Analytical Methods for Pesticides*, NAS-NRC Publication No. 241—Sec. I, December, 1952; Sec. II, September, 1954.

[9] *The Use of Chemical Additives in Food Processing*, NAS-NRC Publication No. 398, February, 1956.

1956. The list contains the names of all additives for which authoritative evidence for use was obtained during a study that required about three years. There are about 500 additives named in the compilation. This compilation, along with an introduction which discusses the functions of additives, has served to give some dimension to discussions of the problems associated with use of chemicals in food processing. The committee is now actively working on a revision of this report—attempting to bring it up to date, to correct it where indicated and to give it more value by improving the quantitative aspects of the information.

A similar project has resulted in a report [10] on the composition and functions of materials used in food packages. This report includes a compilation of chemicals used in food-packaging materials, some discussion of their functions and a general description of means for evaluating safety of the packaging materials for use with foods. The report is meant, again, to indicate the dimensions of the problems associated with assuring safety of packaging materials for use with foods. It does not pose as a definitive or exhaustive technical treatise on manufacture or formulation.

A continuing flow of suggestions for committee action comes from the liaison panel of the committee. There are now under consideration suggestions that FPC direct, or participate in, the compilation and maintenance of a national codex of food additives (a bromatopoeia); that the committee attempt to provide guidance for interested agencies in developing a basis for establishing tolerances more satisfactory than the present rule-of-thumb 100-to-1 safety factor; and that the committee attempt to indicate the kind of investigations needed to develop more definitive and less costly methods for evaluating safety than those now generally used. The committee has also been asked to help sponsor and plan a conference on toxicology and is actively participating in that project.

These organized activities claim most of the time of the committee. It serves, in addition, however, as the academy-research council body to which requests for advice on matters pertaining to food additives are referred. In this respect, for example, the committee recommends rosters of scientists from which the academy-research council

[10] *Food Packaging Materials — Their Composition and Uses*, NAS-NRC Publication 645, November, 1958.

selects scientists to serve on Food and Drug Administration advisory committees to consider proposals for pesticide tolerances; it organized a panel of scientists to discuss with a congressional committee scientific aspects of proposed legislation to amend the Food and Drug Law; and it selected a committee to review FDA research on coal tar colors. Less formally, it participates with government agencies and industry groups in discussions of problems having to do with public health aspects of the use of food additives.

To document this review of the activities of the Food Protection Committee, the published or projected reports of the committee have been referred to. These documents are the end products of discussions in which the guiding principles are the minimizing of bias and the elimination of emotional aspects of the questions being considered. The provision of a forum where questions that are too frequently emotionally charged can be reasonably debated may be the most important activity and achievement of the committee. **[The End]**

SEIZURE OF "HEALTH FOODS" IN LAST 12 MONTHS VALUED IN EXCESS OF $1 ½ MILLION

At a News Conference in Washington on September 22, 1960, Arthur S. Flemming, Secretary of Health, Education, and Welfare made the following statement:

"Commissioner Larrick informs me that the Food and Drug Administration, during the last 12 months, has seized falsely promoted vitamins, minerals and other 'health foods' valued in excess of one-and-a-half million dollars.

"This continuing crackdown has resulted in 25 completed seizure actions and 6 terminated criminal prosecutions. Forty-three additional seizures and two criminal prosecutions are pending in the Federal courts.

"Commissioner Larrick tells me that the amount of misinformation, pseudo-science, and plain 'hokum' reaching the public through books and magazine articles is on the rise. These books and magazine articles often help materially in the false promotion of dietary fads and frauds.

"For example, the current best-selling book, *Folk Medicine*, prescribes unpasteurized honey and apple-cider vinegar for preventing or treating 60 conditions or classes of conditions ranging from heart attacks to falling hair. No legal action appears possible to prevent the publication of this medical nonsense. However, when a mixture of unpasteurized honey and apple-cider vinegar was offered for sale, accompanied by the book, the Food and Drug Administration was able to seize the book as 'labeling' under the Food, Drug, and Cosmetic Act. This is the exception, however. Usually the book or magazine article does not accompany the product."

Mr. Flemming added that vitamin and mineral products serve a useful purpose when the diet requires supplementation, but the uninformed consumer should not resort to self-diagnosis.

By EVERETT I. WILLIS

Product Liability Without Fault:

I HAVE BEEN ASKED to discuss the subject of product liability in the drug industry. That problem is no mere cloud on the horizon. It is with us right now. I would like to suggest, however, that some aspects of this problem have long-range implications which the industry must prepare to meet.

The subject of product liability is receiving particular attention in the drug industry at the moment, largely because of the *Cutter* polio vaccine cases. There, as you all know, a California jury brought in a specific finding that Cutter Laboratories had not been negligent in the preparation of its vaccine, but nevertheless awarded substantial damages to two plaintiffs on the theory of implied warranty.[1]

Therefore, I am going to focus particularly upon the law of implied warranties in drug cases and on similar legal theories which may be used by courts to impose strict product liability upon sellers of drugs. While actual negligence and express warranties may create risks of liability for the industry, those risks are avoidable. The scope of my comments will be limited to what I might describe as the unavoidable risk: the risk of liability without fault.

Even narrowed down in that way, however, there is far more law on the subject than I can possibly cover in the time available. Therefore, I shall allow myself the luxury, for a lawyer, of drawing some general conclusions about the law in this area and the business problems,

[1] *Gottsdanker v. Cutter Laboratories, Inc.* and *Phipps v. Cutter Laboratories, Inc.*, CCH Food Drug Cosmetic Law Reports ¶ 22,543, 22,544 (Cal. Super., 1958), which will be referred to as the "*Cutter* cases." The California Supreme Court refused to disturb the trial court's judgments awarding a total of $267,000 (F. D. C. Reports—Pink Sheet, p. 20, September 12, 1960). Cutter has also been found liable in four additional cases in California, again on a theory of implied warranty (F. D. C. Reports—Pink Sheet, p. 14, October 27, 1958). But cf. *Spencer v. Cutter Laboratories*, (DC Calif., 1956), where the federal district court granted Cutter's motion to dismiss the warranty counts for failure to state a cause of action. The court held that under the applicable law, that of Tennessee, product liability actions against manufacturers may be based only on negligence.

lt: Some Problems and Proposals

This Address by Mr. Willis, Which Was Delivered Before the National Drug Trade Conference on December 11, 1958, Has Been Revised to Reflect Several Developments Since the Date of Its Original Delivery.

both immediate and long-range, it raises for the drug industry. Later on, I shall attempt to suggest some possible directions in which a solution to these problems might be sought.

There is no doubt that the risks of product liability are infinitely greater than they were, say, 25 years ago. The risks have increased only partly as a result of changes in the law. The law has changed, of course, in the last 25 years. It is changing still. But the really significant development has been the enormous advance in research, manufacture and distribution methods which has made available unprecedented numbers of new products to unprecedented numbers of people in the fight against disease. These technological advances have not only multiplied fantastically the number of new medical drugs, but also have made these new products available to the public with unprecedented speed.

The result has been, in effect, a revolution in the American drug industry based upon scientific achievements unsurpassed by any other industry in our highly scientific age. At the same time these very advances in drug technology and marketing have brought with them increased risks in the field of product liability. Thus, in a very real sense, the American drug industry is in danger of becoming the victim of its own excellence.

The *Cutter* cases have attracted wide attention because they illustrate in a rather breathtaking way the enormous risks inherent in the manufacture and sale of modern medicines. In that respect the outcome was startling from a businessman's point of view, and perhaps even more so from an insurance man's point of view. On the other

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hand, despite the contrary impression which may have been conveyed by some of the press reports, the legal issues involved in the cases are not novel. Strict liability in implied warranty has been the rule in a majority of states for a great many years. Moreover, California had abandoned the requirement of privity of contract in actions for breach of warranty in food cases years ago.[2] Thus, from a lawyer's point of view, the legal theory on which the cases were decided is not particularly shocking.

The recognition that sellers of products for human consumption have a special responsibility for the safety of their goods goes back at least four centuries in the English common law.[3] In this country, liability without proof of actual negligence has been imposed on producers and purveyors of human food products in cases going back more than 100 years.[4] One legal path to this end, within the traditional common law tort framework, is the doctrine of *res ipsa loquitur*. This means, in product liability cases, that if a product causes an injury which would not ordinarily have occurred had the product been manufactured with due care, that fact alone is prima-facie evi-

[2] *Klein v. Duchess Sandwich Company*, 14 Cal. 2d 272, 93 P. 2d 799 (1939).

[3] See n. 16, Kielway's Rep. 91, 72 English Reprint 254 (1507), where a judge of the King's Bench stated that a food vendor would be liable for injuries caused by impure consumables whether or not he warranted them, while a vendor of nonconsumables would incur liability only if he had warranted the goods or fraudulently deceived the consumer. See, also, 3 Blackstone's Commentaries 165 (1769), in which it is stated that "In contracts for provisions, it is always implied that they are wholesome."

[4] See, *e. g.*, *Van Bracklin v. Fonda*, 12 John. 468 (N. Y. Sup. Ct., 1815). There, though the seller knew of the defect, the court stated that "In the sale of provisions for domestic use, the vendor is bound to know that they are sound and wholesome, at his peril." See, also, *Divine v. McCormick*, 50 Barb. 116 (N. Y. Sup. Ct., 1867), and *Hoover v. Peters*, 18 Mich. 51 (1869).

dence that the accident was caused by the manufacturer's negligence.[5] In other words, the doctrine has the effect of shifting to the defendant the heavy burden of convincing the jury that he exercised due care.[6]

The principal legal theory that imposes liability without fault on drug manufacturers, wholesalers and retailers is that of implied warranty. This concept, which had its origins in the common law, is found today in the sales acts in force in most states.[7] These acts impose two kinds of implied warranties that are pertinent to this discussion: a warranty of fitness for a particular purpose[8] and a warranty of merchantability.[9] Where a product is manufactured and sold for human consumption, both these warranties are broken if the product is, in fact, unfit for human consumption.[10] Thus, in the

[5] For an example of application of the doctrine in a food case, see *Miller v. Meadville Food Service*, 173 Pa. Super. 352, 98 A. 2d 452 (1953).

[6] The doctrine of *res ipsa loquitur* is commonly thought to apply, in the context of manufactured products, only to manufacturers because of the requirement that the cause of the injury must have been within the exclusive control of the defendant. However, courts have sometimes applied the doctrine in cases in which intermediate vendors were joined with the manufacturer as defendants, on the theory that the defendants should determine among themselves which of them had exclusive control at the time the product acquired the defect. See, *e. g., Nichols v. Nold*, 174 Kan. 613, 258 P. 2d 317, 320-323 (1953) (an exploding bottle case) and cases cited therein.

Another tort theory which results in the imposition of product liability without actual negligence is the rule that a nonmanufacturing vendor who relabels the product and sells it under his own trade name thereby becomes liable for the negligence of the actual manufacturer. See, *e. g., Commissioners of State Insurance Fund v. City Chemical Corporation*, 290 N. Y. 64, 48 N. E. 2d 262 (1943).

In many jurisdictions, violation of a pure food and drug statute constitutes negligence in itself, without regard to due care. In others, violation of such statutes is considered only evidence of negligence; but even in those cases the effect is to shift the burden of going forward on the issue of negligence from the plaintiff to the defendant. See Prosser, *Torts* (2d Ed., 1955), pp. 161, 345.

[7] The Uniform Sales Act is in effect in 34 states, the District of Columbia and the Canal Zone. See Table III, 1957 Uniform Sales Act Pocket Part at p. 6 for a list of the states in which it is effective. Massachusetts and Pennsylvania, former sales act states, have recently enacted the Uniform Commercial Code, which contains similar provisions as to implied warranty. Massachusetts Annotated Laws, Ch. 106 (1957); Pennsylvania Statutes Annotated, Tit. 12A (1953).

[8] Uniform Sales Act, Sec. 15(1).

[9] Uniform Sales Act, Sec. 15(2).

[10] Where a specified article is purchased by its patent or other trade name, there is no implied warranty as to its fitness for any particular purpose. Uniform Sales Act, Sec. 15(4). There is no such restriction on the warranty of merchantability, however. Since at a minimum both warranties require that foods or drugs be safe for human consumption, the implied warranty of merchantability will always be available to an injured consumer as a basis for suit, even where purchase by patent or trade name negates the warranty of fitness for a particular purpose. 1 Williston, *Sales* (Rev. Ed., 1948), Sec. 236a.

Cutter cases the trial judge instructed the jury that warranties of fitness and of merchantability were involved. The result is that the sales acts themselves impose strict liability on manufacturers and distributors of food and drug products wherever injury is caused.

Decline in Adherence to Rule of Privity

Thus far, I have been speaking of strict liability, that is, liability for personal injuries without regard to actual negligence. I have tried to point out, moreover, that strict liability in food and drug cases has been the general rule for quite some time. Where there *is* a noticeable change in the law, a change which is taking place right now, is in the increasing disposition of courts to impose *direct* liability on manufacturers whose products cause personal injuries. I refer, of course, to the marked decline in adherence to the rule of privity. Where the privity rule is still respected—for instance, in New York [11] —an action in warranty can be brought only against the plaintiff's immediate vendor. Where the action is based on an implied warranty, the defendant vendor—in most cases, the retailer—can bring an action over against his vendor, the wholesaler, who can in turn recover from his vendor, the manufacturer. The point to notice is that in a case involving an injury resulting from consumption of a drug product, the manufacturer would always, in theory, be *strictly* liable in warranty, but only indirectly, that is, as the ultimate link in the privity-chain.

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[11] *Chysky v. Drake Brothers Company*, 235 N. Y. 468, 139 N. E. 576 (1923) (food); *Wechsler v. Hoffman-La Roche, Inc.*, 198 Misc. 540, 99 N. Y. S. 2d 588 (Sup. Ct., 1950) (prescription drug). The privity doctrine has been undergoing progressive erosion in New York. See *Ryan v. Progressive Grocery Stores, Inc.*, 255 N. Y. 388, 175 N. E. 105 (1931), where a husband was allowed to recover, although the food had been purchased by his wife; *Bowman v. Great Atlantic and Pacific Tea Company*, 284 App. Div. 663, 133 N. Y. S. 2d 904 (4th Dept., 1954), aff'd, 308 N. Y. 780, 125 N. E. 2d 165 (1955), where one of two sisters living together was allowed to recover for injuries sustained from food purchased by the other.

However, the courts have refused to erode the doctrine further. *Greenberg v. Lorenz*, CCH Food Drug Cosmetic Law Reports ¶ 22,638, 7 App. Div. 2d 968, 183 N. Y. S. 2d 46 (1st Dept., 1959), leave to appeal granted, 8 App. Div. 2d 609, 185 N. Y. S. 2d 740 (1st Dept., 1959); *Burke v. Associated Coca-Cola Bottling Plants, Inc.*, CCH Food Drug Cosmetic Law Reports ¶ 22,587, 7 App. Div. 2d 942, 181 N. Y. S. 2d 800 (3d Dept., 1959); *Papp v. Jackson Manufacturing Company*, 8 App. Div. 2d 637, 185 N. Y. S. 2d 872 (2d Dept., 1959), leave to appeal granted, 6 N. Y. 2d 845, 160 N. E. 2d 86 (1959). The privity question is now with the New York Court of Appeals. See Hart, "Commercial Law," 34 *New York University Law Quarterly* 1442 (1959).

Although privity is still a requirement in some states in all warranty actions,[12] it has not been required in several states for the past three decades, at least where food products are concerned.[13] The requirement that there be a contractual, or "privity," relationship between the injured consumer and the defendant crumbled first in the food area. Once this was gone, the way was open for the injured consumer to sue the manufacturer of the product directly. That the exception to the privity requirement should be extended from the food to the drug field is not surprising, considering that both products affect the human body.[14]

The current decline in adherence to the rule of privity in warranty actions repeats the history of what amounted to a privity requirement in the law of negligence. There the requirement of privity was first abolished in cases of injuries resulting from "inherently dangerous" products such as drugs,[15] explosives,[16] food,[17] drink [18] and firearms.[19] This category was gradually expanded, until it extended to all articles which would be dangerous if negligently made.[20]

I need hardly point out that the progressive decline of privity as a requirement in warranty actions lifts some of the burdens of product liability from drug wholesalers and retailers. On the other hand, I

[12] See, *e. g., Russell v. First National Stores, Inc.*, 96 N. H. 471, 79 A. 2d 573 (1951); *Whitethorn v. Nash-Finch Company*, 67 S. D. 465, 293 N. W. 859 (1940); *Minutilla v. Providence Ice Cream Company*, 50 R. I. 43, 144 A. 884, 63 A. L. R. 334 (1929). Other cases are cited in Prosser, *Torts* (2d Ed., 1955), p. 510, and 1 Williston, *Sales* (Rev. Ed., 1948), Sec. 244, n. 12.

[13] See, *e. g., Mazetti v. Armour & Company*, 75 Wash. 622, 135 P. 633 (1913); *Davis v. Van Camp Packing Company*, 189 Iowa 775, 176 N. W. 382, 17 A. L. R. 649 (1920); *Ward Baking Company v. Trizzino*, 27 Ohio App. 475, 161 N. E. 557 (1928); *Klein v. Duchess Sandwich Company*, cited at footnote 2; *Patargias v. Coca Cola Bottling Company of Chicago*, 332 Ill. App. 117, 74 N. E. 2d 162 (1947). Other cases are cited in Prosser, *Torts* (2d Ed., 1955), p. 508, and 1 Williston, *Sales* (Rev. Ed., 1948), Sec. 244, n. 13. See, also, 142 A. L. R. 1494 and prior annotations cited therein.

[14] See *Rogers v. Toni Home Permanent Company*, 167 Ohio St. 244, 147 N. E. 2d 612, 614 (1958); *Graham v. Bottenfield's, Inc.*, 176 Kan. 68, 269 P. 2d 413, 418 (1954).

[15] *Thomas v. Winchester*, 6 N. Y. 397, 57 Am. Dec. 455 (1852); *Blood Balm Company v. Cooper*, 83 Ga. 457, 10 S. E. 118 (1889).

[16] *Wellington v. Downer Kerosene Oil Company*, 104 Mass. 64 (1870).

[17] See, *e. g., Tomlinson v. Armour & Company*, 75 N. J. L. 748, 70 A. 314 (1908).

[18] See, *e. g., Boyd v. Coca Cola Bottling Works*, 132 Tenn. 23, 177 S. W. 80 (1910).

[19] See, *e. g., Welshausen v. Charles Parker Company*, 83 Conn. 231, 76 A. 271 (1910).

[20] *MacPherson v. Buick Motor Company*, 217 N. Y. 382, 111 N. E. 1050 (1916).

cannot encourage wholesale and retail druggists to suppose that, in the absence of a privity requirement, they can wash their hands of the whole problem and leave it to the manufacturers.

For one thing, the abandonment of privity permits actions by persons who could not previously sue in warranty at all.[21] Warranty actions thus become available to injured consumers of drug products who previously would have had to make a case in negligence. And while these plaintiffs *may* bring a drug warranty action against the manufacturer of the product, there is no certainty that they will do so in any particular case. It may be simpler to move against a financially responsible retailer or wholesaler, particularly where such a retailer or wholesaler can be served within the jurisdiction of a local court.[22]

Shift in Social Philosophy

At this point we might consider why it is that courts feel obliged to ease the path of recovery for injured consumers of foods, drugs and other products. This, I think, is explained by a shift in our social philosophy. It was typical of the social viewpoint of the nineteenth century that to hold manufacturers and sellers responsible to unlimited numbers of persons whose identity they did not know would place too heavy a burden on the relatively weak industrial economy of that day. Accordingly, courts felt that it was better to let the consumer suffer.

[21] See, for example, the New York cases cited in footnote 11, permitting relatives of purchasers to sue those with whom only the purchaser is in privity of contract. Similarly, Sec. 2-318 of the Uniform Commercial Code (1957 Official Text) states that:

"A seller's warranty whether express or implied extends to any natural person who is in the family or household of his buyer or who is a guest in his home if it is reasonable to expect that such person may use, consume or be affected by the goods and who is injured in person by breach of the warranty. A seller may not exclude or limit the operation of this section."

It has been held in New York that blood transfusions administered by a hospital are supplied as part of a service, rather than as a sale, with the result that the warranties imposed by the sales act do not apply. (*Perlmutter v. Beth David Hospital*, 308 N. Y. 100, 123 N. E. 2d 792 (1954).) Thus, in New York, where the privity rule is still in effect, a processor of blood would be free of warranty liability since a hospital, having incurred no liability, would have no occasion to seek recovery over from the processor. However, were New York to abolish the privity rule, the processor would become subject to the risk of liability for breach of warranty, since an injured patient could then sue him directly. The *Perlmutter* result was codified in California. (California Health & Safety Code Sec. 1623 (1955).) In California, however, the statute protects processors as well as distributors of blood and blood products.

[22] See, *e. g., Graham v. Bottenfield's, Inc.*, cited at footnote 14.

From the 1920's on, there has been a continuous and almost unanimous stream of professional legal writing attacking this notion.[23] Underlying the judicial decisions abolishing privity is the theory put forth by these writers that the risks of life in an industrial society should be borne not by individuals but by those in a position to distribute the loss, and that the loss should be placed at the point at which the most pressure can be exerted to keep down future losses.

The conclusion drawn from these aims is that the burden of accidental injuries caused by defective products should be placed upon the producer. He, in theory, is best able to distribute the risk to all the users of the products involved by means of insurance and increased prices. The argument is that where the producer is subject to strict liability, he is given an incentive to exercise the greatest possible care. Since this social policy seems increasingly to be receiving approval in the courts, it is doubtful that the trend could be reversed at this date.

If I may be allowed to summarize in very general terms, I would say that the liability which the law imposes today on the manufacturers, wholesalers and retailers of drug products is no stricter, in a legal sense, than it was a quarter of a century ago. That liability is becoming broader, however, in the sense of extending to a larger class of people, through the abolition of the privity requirement. Moreover, juries seem to be getting increasingly lavish in their awards.

Developments in the industry itself have also made product liability a more and more serious problem. A quarter of a century ago the number of new products developed annually was nowhere near what it is today; nor were there facilities for bringing new medicinal drugs into quick and wide public distribution. It used to be that drug manufacturers produced, for the most part, remedies which had stood

[23] See, *e. g.*, Perkins, "Unwholesome Food as a Source of Liability," 5 *Iowa L. Bull.* 6, 86 (1919); Patterson, "The Apportionment of Business Risks Through Legal Devices," 24 *Columbia Law Review* 335 (1924); Llewellyn, *Cases and Materials on the Law of Sales* (1930), p. 204; Jeanblanc, "Manufacturers' Liability to Persons Other Than Their Immediate Vendees," 24 *Virginia Law Review* 134 (1937); Feezer, "Manufacturers' Liability for Injuries Caused by His Product," 37 *Michigan Law Review* 1 (1938); Spruill, "Privity of Contract as a Requisite for Recovery on Warranty," 19 *North Carolina Law Review* 551 (1941); Dickerson, *Products Liability and the Food Consumer* (1951), pp. 93-156; Prosser, *Torts* (2d Ed., 1955), p. 506; Note, "The Cutter Polio Vaccine Incident: A Case Study of Manufacturers' Liability Without Fault in Tort and Warranty," 65 *Yale Law Journal* 262 (1955).

the test of years of experience. Under those conditions, it is easy to see that in the infrequent cases where an injury resulted, there was likely to have been some error in the process of manufacture. That meant that plaintiffs were generally able to make out a case of actual negligence, and did not need to rely very often on the concept of liability without fault.

At the same time, when a new product was put on the market, it was likely to be some years before it achieved very wide acceptance among the medical profession and consumers generally, so that there was an opportunity to iron out any difficulties in production and testing methods, and to discover any unforeseen side effects while the number of people who might possibly be injured was relatively limited. Generally speaking, therefore, the danger of product liability in the drug industry, viewed as an insurance risk, was at least finite.

For contrast, consider the industry's situation today. Since World War II the industry has probably made more novel contributions to the fight against disease than were made in the preceding 50 years. One pharmaceutical manufacturer reports that almost half its sales volume in 1957 was in products introduced within the preceding five years.[24] Production and distribution methods have also been expanded, so that a new product can be widely available within a matter of months after its discovery.

These developments have resulted in vastly increased risks of product liability. More new products are available to more people more quickly. Consequently, when injuries result from unforeseen side effects, there is a possibility that the number of claims may be very substantial by the time the effect becomes known.

Similarly, many of the new products coming onto the market involve manufacturing and testing techniques of incredible complexity. They are constantly subject to change and improvement as chemical and biological research pushes back the borders of the unknown. To withhold the benefit of new discoveries from the public over years of precautionary testing would be no service to society.

Take the Salk vaccine story as a concrete example. The testing methods used by Cutter in 1955 were deemed adequate by all the authorities on the subject at that time. Other procedures have been

[24] Eli Lilly & Company, *Report to the Shareholders—1957*, p. 9.

developed since. However, no one could deny that the public benefit of making polio vaccine available for inoculating children that summer of 1955 vastly outweighed the injuries which occurred. Had it not been for the vaccine, the number of children stricken with polio during that and later years would have been infinitely greater.

Thus there is a tremendous social advantage—I believe it could be called a public policy—in having new medical discoveries widely available with the least possible delay. The problem facing the industry, then, is how to continue its present progress and public service without exposing itself to the risk of ruinous product liability.

The first device that comes to mind for protecting manufacturers and distributors in this respect is the familiar one of product liability insurance. Insurance of that kind has come to be generally relied on throughout the industry, and, so far as I am aware, has proved, on the whole, satisfactory in the past.[25] More recently, however, the companies that write product liability policies have become increasingly alarmed at the size of the claims that they are called upon to meet. One example, of course, is the Cutter incident; there have been others, less publicized but nevertheless substantial.

I have heard it suggested that it will become increasingly difficult for members of the drug industry to obtain adequate coverage anywhere. There seems, at present, to be no insurance market for coverage on the $10 million to $20 million liabilities that major drug producers must consider as not beyond the realm of possibility. There are indications that premiums will rise, and that insurance carriers will be lowering limits, rather than raising them.

In the short-term future it is likely that some solution can be found through a reappraisal and revision of the traditional system of product liability insurance. Considerable thought is being devoted to this subject by responsible people in the insurance business. However, in the final analysis, insurers will cover only calculable risks, while the risk of product liability appears to be getting less calculable every year.

Another possible approach which deserves serious thought is in the area of disclaimer. Liability without fault is most likely to be imposed on the contract theory of implied warranty. This suggests immediately the possibility that sellers may be able to "contract out"

[25] Amounts paid as damages in product liability actions will ordinarily be deductible, to the extent not compensated by insurance, for corporate income tax purposes. Internal Revenue Code of 1954, Sec. 165.

of this kind of liability by means of express language incorporated in the conditions of sale.

There has been surprisingly little litigation over the effect of warranty disclaimers in the sale of drug products, and the case law on disclaimers in other fields varies widely from state to state. The Uniform Sales Act states that an express condition does not negative an implied warranty, unless it is inconsistent therewith.[26] Therefore, as a general rule, disclaimers must be stated in rather strong and specific language in order to avoid liability under the warranties imposed in law.[27] Of course, there is always a business judgment to be made regarding the effect of disclaimers of warranty on sales and on the reputation and good will of the seller. I am not suggesting, however, that disclaimers be used indiscriminately.[28] Rather I am suggesting that disclaimers might be helpful in the areas where the hazards are greatest: the introduction of important new medicinal discoveries, where there is not sufficient experience to enable manufacturers to foresee all the possible effects of the product on all the possible variations of the human system.[29]

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[26] Uniform Sales Act, Sec. 15(6).

[27] As a general rule, disclaimers of implied warranties of quality are strictly construed against the seller. See Prosser, "The Implied Warranty of Merchantable Quality," 27 *Minnesota Law Review* 117, 160, 162 (1943). For example, in *Burr v. Sherwin Williams Company*, 42 Cal. 2d 682, 268 P. 2d 1041 (1954), the plaintiff's cotton crop had been damaged by the defendant's insecticide spray. The following language was held inadequate to bar recovery on the implied warranty of merchantability:

"Seller makes no warranty of any kind, express or implied, concerning the use of this product. Buyer assumes all risk in use or handling, whether in accordance with directions or not." (268 P. 2d, at p. 1047.)

The court reasoned that the damage had been caused by impurities in the spray, and that the disclaimer did not convey to a buyer the seller's unwillingness to warrant against impurities.

The language of precautionary directions is likewise strictly construed. See *Schilling v. Roux Distributing Company, Inc.*, 240 Minn. 71, 59 N. W. 2d 907 (1953).

[28] Widespread use of disclaimers on drug products might encourage courts to declare them void as contrary to public policy. For one such opinion, where a food processor had attempted to disclaim implied warranties, see *Linn v. Radio Center Delicatessen, Inc.*, 169 Misc. 879, 9 N. Y. S. 2d 110 (N. Y. C. Munic. Ct., 1939).

In *Henningsen v. Bloomfield Motors, Inc.*, 32 N. J. 358, 161 A. 2d 69 (1960), the New Jersey Supreme Court held that the standard automobile manufacturer's disclaimer of warranties was void as against public policy. Contra, *Haas v. Buick Motor Division*, 20 Ill. App. 2d 448, 156 N. E. 2d 263 (1959); *Grayson Motor Sales, Inc. v. Shannon*, 322 S. W. 2d 465 (Ky., 1959); *Wilson v. Eargle*, 98 Ga. App. 241, 105 S. E. 2d 474 (1958). Accord, *Stryker v. Rusch*, 8 App. Div. 2d 244, 187 N. Y. S. 2d 663 (3d Dept., 1959).

[29] There is a split of authority as to whether the plaintiff's allergy or abnor-

Let us assume that a manufacturer introducing a new drug has words such as the following clearly printed on the package: "We believe this product to be safe if used under the direction of a physician (or in accordance with the accompanying directions). We cannot guarantee, however, that use of this product will not produce unfortunate results in some persons. This product is sold without warranty, express or implied, against injuries resulting from its use." It seems to me that a court considering such a disclaimer, and having urged upon it the benefit which the public derives from having new drug discoveries made available with the least possible delay, might well conclude that an injured plaintiff had been adequately informed of the risk which accompanies advances in drug technology, and had elected to assume that risk.

A similar disclaimer might be attached, by means of a sticker or a rubber stamp, by wholesalers and retailers, where there is no disclaimer on the label. Wholesalers and retailers who sell products in sealed containers have no opportunity for inspection, and there is an obvious unfairness in holding them liable on an implied warranty of quality. This unfairness has been recognized by some courts.[30]

(Footnote 29 continued)

mal sensitivity to a product affords a defense to a suit for breach of an implied warranty of quality. In most jurisdictions such a defense will relieve the manufacturer of liability for harm caused. See *e. g., Bonowski v. Revlon, Inc.*, CCH Food Drug Cosmetic Law Reports ¶ 22,635, 100 N. W. 2d 5 (Iowa, 1959); *Hanrahan v. Walgreen Company, Inc.*, 243 N. C. 268, 90 S. E. 2d 392 (1955); *Barrett v. S. S. Kresge Company*, 144 Pa. Super. 516, 19 A. 2d 502 (1941); *Ross v. Porteous, Mitchell & Braun Company*, 136 Me. 118, 3 A. 2d 650 (1939). See, generally, 26 A. L. R. 2d 963. A few courts hold, however, that such unusual sensitivity is no defense to a warranty action. See, *e. g., Reynolds v. Sun Ray Drug Company*, 135 N. J. L. 475, 52 A. 2d 666 (1947); *Zirpola v. Adam Hat Stores*, 122 N. J. L. 21, 4 A. 2d 73 (1939); *Bianchi v. Denholm & McKay Company*, 302 Mass. 469, 19 N. E. 2d 697 (1939).

Where the manufacturer knows or ought to know that his product will be harmful to the unusually susceptible consumer, he is under a duty to warn of the known hazard, and will be liable in negligence for failure to do so. *Wright v. Carter Products, Inc.*, 244 F. 2d 53 (CA-2, 1957) (applying Massachusetts law).

Federal law imposes criminal penalties upon drug sellers who fail to give warning of known hazards to any given class of potential users. Federal Food, Drug, and Cosmetic Act, Secs. 301, 303, 502(f), 52 Stat. 1042, 1050 (1938), as amended, 21 USC Secs. 331, 333, 352(f) (Supp. V, 1953).

[30] See, *e. g., Bowman Biscuit Company of Texas v. Hines*, 151 Tex. 370, 251 S. W. 2d 153 (1952); 1 Williston, *Sales* (Rev. Ed., 1948), Sec. 242, n. 13. Against this recognition must be weighed a court's natural desire to provide some avenue of relief for the injured. Thus, in a jurisdiction which retains the privity rule, an injured plaintiff who is barred from recovering against his immediate seller, usually a retailer, is thereby de-

(Continued on following page)

Other courts have held, however, that an implied warranty of merchantability arises from every sale, regardless of the seller's opportunity for inspection.[31] In such jurisdictions, wholesalers and retailers might find some protection in disclaimers.

There is, on the other hand, one serious stumbling block to the use of disclaimers by manufacturers and wholesalers of medicinal drugs. Where there is a claim of injury arising from the use of a medicinal drug, it will frequently turn out that the drug was administered by a physician or a hospital. In these circumstances the injured patient is not made aware of any disclaimer. The result is that a disclaimer would probably be no defense in such a case, since a disclaimer does not normally bind a purchaser without notice of its terms.[32] Thus, although disclaimers may afford some protection against liability in warranty, I cannot recommend them as an adequate substitute for liability insurance at the highest limits obtainable.

So far I have indicated very generally the nature of some of the problems in the field of product liability which face the industry today. It is always hazardous to attempt predictions, but it seems to me that these problems are more likely to increase than to diminish over the next few years. The day may come when the manufacturers and sellers of newly discovered drug products find themselves facing an almost unlimited risk of liability: a risk which cannot be avoided by even the most meticulous care, which cannot be adequately insured against and which cannot be effectively disclaimed.

If that day comes, if product liability risks become both unavoidable and unlimited, a point could be reached at which the industry would find itself compelled to curtail the magnificent public service which

(Footnote 30 continued)
nied any compensation, unless he meets the often difficult requirement of proving actual negligence. However, where a plaintiff has the option of direct recourse against the manufacturer, it would seem that no policy argument favors holding liable wholesalers or retailers of goods in sealed containers. For a contrary view, see *Graham v. Bottenfield's, Inc.*, cited at footnote 14.

[31] See, *e. g.*, *Rogers v. Toni Home Permanent Company*, cited at footnote 14 (hair preparation); *Greenberg v. Lorenz*, 12 M. 2d 883, 178 N. Y. S. 2d 407 (App. T., 1958) (food); *Graham v. Bottenfield's, Inc.*, cited at footnote 14 (hair dye); *Reynolds v. Sun Ray Drug Company*, cited at footnote 29 (lipstick); *Ryan v. Progressive Grocery Stores, Inc.*, cited at footnote 11 (food); 1 Williston, *Sales*, Sec. 242, indicating that a majority of courts hold the retailer and wholesaler liable.

[32] Williston, *Sales* (Rev. Ed., 1948), Sec. 239c. See, also, Annotation, 160 A. L. R. 357, where notice problems are discussed at length.

it renders today. Wholesalers and retailers would be forced to shy away from the distribution of newly developed products. Manufacturers would have to hold new discoveries off the market for long periods, perhaps years, of controlled testing. Indeed, the very incentive to continue research in new fields of prevention and cure of disease would inevitably be reduced. These results would be a tragedy, not only for the drug industry but also for the public. What is needed, therefore, is some means of setting a limitation to the risk of product liability.

I cannot, I am sorry to say, hold out much hope for a limitation of liability in the courts. There is, as I pointed out earlier, a very strong policy argument against letting risks of this kind fall upon individual injured plaintiffs. Moreover, we must bear in mind that judges and juries have to decide individual cases, and it is not surprising if they are unwilling to place the unavoidable costs of progress upon the injured. The basic problem is to arrive at some accommodation between two understandables, but to some extent conflicting, social policies: (1) the policy that favors spreading the risk of injury as widely as possible by placing it, in the first instance, on manufacturers and sellers, and (2) the policy that favors a continuation of the discovery and rapid distribution of new drugs. This accommodation, I think, would have to be sought through legislation.

Therefore, I suggest that consideration might be given to a statutory limitation of the warranty liability of drug sellers. The statutory ceilings on recoveries in tort actions for wrongful death, which have been enacted in 15 states, provide precedent for such a measure.[33] An effort might be made to extend this concept of limited liability to apply to warranty, as well as tort actions, and to include personal injuries not resulting in death. However, any limitation in the form of a maximum recovery for each plaintiff is subject to two disadvantages: It would be unfair to plaintiffs with serious compensable injuries. It

[33] In 1956 such statutes were in force in Alaska, Colorado, Illinois, Indiana, Kansas, Maine, Minnesota, Missouri, New Hampshire, Oregon, Rhode Island, South Dakota, Virginia, West Virginia and Wisconsin. Limitations on recoveries ranged from $7,500 (New Hampshire) to $25,000 (Illinois, Kansas, Missouri, Rhode Island and Virginia). See comparative table in 5 *Cleveland-Marshall Law Review* 130 (1956).

Another example of limited liability based on a stated maximum for each individual recovery is the Warsaw Convention on International Air Transportation, adhered to by the United States on October 29, 1934. 49 Stat. 3000. Art. 22 of the convention limits the liability of air carriers for personal injuries arising in international flights to $8,291.87 per passenger, except in the event of willful misconduct by the carrier.

would also fail to provide a system whereby the drug industry would be in a position to calculate its risks, since the number of persons who might be injured in a given incident would be impossible to predict.

What I have in mind is something analogous to the limitation of liability which we find in the law of admiralty.[34] That limitation was provided by statute more than a century ago. It was provided, quite frankly, to encourage the shipping industry, the theory being that the risks of major marine disasters were so great that unless limited they would discourage investment in a socially useful field. Very briefly, the limitation of liability in admiralty means that, in the absence of negligence on his part, the owner of a vessel can calculate in advance the maximum risk of any single voyage.[35]

A limitation of the liability of sellers of drugs could, I believe, be worked out on similar principles. The limitation figure could be related to the specific product involved—as, for example, by limiting liability for non-negligent injury to a stated percentage of the seller's net sales of that product for the year in which the injuries occurred. Alternatively, the limitation might be set at the figure beyond which insurance coverage is no longer obtainable or economically feasible. In either case the limitation would come into effect only rarely: only in cases of major disaster, analogous, let us say, to the sinking of a vessel at sea. The objective, under any formula, would be to afford a reasonable recovery to injured consumers, while at the same time making the seller's risks finite and calculable.

The question naturally arises whether such statutory relief should be sought at the federal or state level. A statutory limitation of product liability might be drafted and submitted to the state legislatures in the form of a uniform act. A federal statute would, of course, be vastly preferable from the point of view of immediate uniformity. There may be a question as to the constitutionality of a federal statute along the lines I have suggested, but I think it at least arguable that

[34] Act of March 3, 1851, Ch. 43, Sec. 3, 9 Stat. 635, codified in Revised Statutes, Sec. 4283 (1875), amended 49 Stat. 960 (1935), amended 49 Stat. 1479 (1936), now 46 USC Sec. 183.

[35] The limitation applies to all liabilities arising in the course of a single voyage. Liability for property damage is limited to the value of the ship at the end of the voyage plus gross freight and passage money earned on the voyage. In addition, owners of seagoing vessels are liable up to $60 per gross ton of the ship's weight, if necessary to meet claims for personal injury and death. In effect, an owner's maximum losses and liability arising from a single voyage are limited to his investment in the particular ship plus $60 per ton.

such a statute would be constitutional on the very ground which suggests its necessity: as a measure designed to maintain an undiminished flow of new drug products in interstate commerce.[36]

I myself have a strong personal preference for an honest limitation of liability over some of the suggestions which have been made for a federal insurance fund. Federal insurance would, after all, amount to a form of federal subsidy, and I believe that business, in its own interest, should avoid asking for subsidies wherever possible. Moreover, I do not think this problem needs to be solved in that way. A statutory limitation of liability would, by its very nature, become operative only where large numbers of injured plaintiffs were involved. It might, in rare instances, result in some proportionate diminution of the recoveries normally available to such a group, but it would never impose on any individual the whole burden of his loss. Under these circumstances, a limitation statute would carry out the public policy which favors a spreading of the risks inherent in a technological society. Such a system should not be considered too high a price for insuring the continuation of a strong, progressive drug industry.

I have suggested statutory limitation of product liability as a long-range solution to a long-range problem. I do not, of course, believe that such legislation could be successfully advanced this year or next. A lot of premilinary groundwork would need to be done to educate the public and its responsible officials on the enormous contributions which the industry makes to the national health and welfare. It would further be necessary to get across the idea that progress in pharmaceutical and biological research inevitably entails some risks, and that those risks cannot be imposed wholly on the drug industry without serious danger of impairing its ability to serve the public.

This conference, representing as it does all sectors of the national drug industry, is the logical starting point for the exchange and dissemination of ideas. Those of us who believe in the drug industry and its continuing contribution to the public welfare should be prepared to face squarely the ultimate hazards of product liability and begin now to consider the ultimate means to control them. **[The End]**

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[36] Cf. *Wickard v. Filburn*, 317 U. S. 111 (1942), in which the Supreme Court upheld as a valid exercise of the commerce power a federal statute under which "marketing penalties" were assessed against a farmer for wheat raised in excess of acreage allotments, even though it was in fact fed to his livestock. The Court reasoned that the price of wheat in interstate commerce was affected by the amount produced by farmers for their own use.

By L. M. BAUKIN

FDA Labeling Regulations and Their Pertinency to the Practice of

AS A PHARMACIST and a representative of the Food and Drug Administration, I find it a real privilege to be with you to discuss not only some of the drug labeling requirements of the Federal Food, Drug, and Cosmetic Act but also some of the fundamental philosophy which has entered into the development of those labeling requirements. I must say at the outset that I am not, as most of you are, a practicing pharmacist. However, I believe we mutually understand that pharmacy has a real interest in any law that concerns itself with the many aspects of the handling of drug products.

Many provisions of the Federal Food, Drug, and Cosmetic Act are of fundamental importance to the pharmacist. However, probably none of those provisions of the Act has a more direct application to the pharmacist than do the provisions of the Durham-Humphrey Amendment. In substance, this amendment, which became operative in 1952, serves to divide drug products into two major categories: (1) drugs which are identified as "prescription drugs" and which bear on their labels the statement "Caution: Federal law prohibits dispensing without prescription" and (2) drugs which are regarded as suitable for sale over the counter to the laity since adequate directions for such use can be written.

The first category—the prescription drugs—is not only the one about which you find yourselves so vitally interested from a professional standpoint, but it is also one about which we find ourselves so frequently concerned in law enforcement. There are many reasons why we should be necessarily concerned with the handling of prescription drugs. I am sure we all recognize that drugs entitled to be in this category require competent handling by the manufacturer, the

ice of Pharmacy

The Author, Who Is with the Food and Drug Administration, Presented This Paper Before the Joint Session of All the American Pharmaceutical Association Sections During the 1960 American Pharmaceutical Convention in Washington, D. C., August 18, 1960.

practitioner and the pharmacist, in order that the drugs will be beneficial and not detrimental to the public. The pertinency to pharmacy of the "prescription drug" requirements is well known. We might say that this category has a built-in professional linkage, so much so that the ultimate consumer or patient derives the benefits he expects from the workings of this professional control of potent and important drugs. We think it is in the area of prescription drugs that the pharmacist has his greatest opportunity—and, in fact, a delegated legal responsibility—to exercise his full professional training and judgment so that his function as an important cog in the machinery of medicine will be realized.

In talking to a group of this kind, spokesmen for the Administration often speak in some detail about the restrictions the law places on the pharmacist. Although some may feel it unfortunate that we talk about legal restrictions, at the same time, I believe we all recognize that it is unfortunate also that we find, too frequently, the need for emphasizing those restrictions. But when we analyze what these restrictions are intended to accomplish, I think we can agree, too, that prescription drug restrictions tend to support the professional stature of the pharmacist. The restrictions on prescription drug dispensing inherently bring reliance on the pharmacist on the part of the medical profession and the patient. If we recognize this to be a fact, then it is difficult to understand the reasoning, or lack of it, which causes some of our pharmacists to jeopardize their stature as an integral part of the physician-pharmacist-patient relationship by dispensing a potent drug without having a bona fide prescription to

cover the transaction. Actually, the Durham-Humphrey Amendment, while it is restrictive in a literal sense, provides the pharmacist with the responsibility and the opportunity to firmly establish his professional reputation, need and function in the area of public health. If you, as pharmacists, appreciate this, then so will the physicians you work with and the customers you deal with.

In administering the law, we must decide whether the manufacturer or distributor has properly concluded that his product may be labeled with adequate directions for its safe and effective use by the laity. Actually, the manufacturer or distributor does not have unlimited freedom to choose the category in which his drug is placed. The category is determined by definition, and it is a matter for the determination of the court if there is a dispute as to the category into which a drug should fall. During the past 20 years, there have been many drug products which have been introduced in medicine, on both a prescription and over-the-counter basis. Years ago, many of the drugs available for self-medication, and even some for use on prescription, had a common virtue of being relatively innocuous and, too often, were not particularly efficacious in the treatment of disease. The new era which came with the development of the sulfonamide drugs and the many antibiotics served to change this picture.

A current matter which I believe will be of interest is that of a recently published notice of a proposal to revise the labeling regulations. This has to do with the labeling requirements for prescription drugs. The proposed revision of the regulations would require that the immediate package from which the prescription drug is to be dispensed must bear adequate information for use of the drug, including indications; effects; dosages; routes of administration; methods, frequency and duration of administration; any relevant hazards, contraindications and side effects; and precautions under which practitioners licensed by law to administer the drug can use the drug safely and for the purpose for which it is intended. This package labeling would have to include information for proper use of the drug for all purposes for which the drug is advertised or represented. If the drug is a "new drug," a drug containing insulin, or a certifiable antibiotic, the labeling used must be that authorized by the effective new-drug application, or that required as a condition for the certification, or the exempt certification requirements, applicable to preparations of insulin or antibiotic drugs.

The proposed regulation would require further that any brochure or other printed matter which falls into the legal category of "labeling" including those sent to physicians as a mailing piece, etc., and which furnishes or purports to furnish any dosage or other information for use, shall also contain the complete information just described, and, in addition, the ingredients of the drug as listed on the label and the date of issuance of the labeling.

The primary responsibility for the drug being properly labeled as received by the pharmacist would continue to rest with the manufacturer, packer or distributor of the article. However, what could we anticipate would be the effect on the pharmacist of such an amended regulation? You will note that it will bring into one place, in immediate association with the product itself, all of the information necessary for the physician to safely and effectively prescribe or use the drug. It will make available for ready access all the necessary information for review by the physician and pharmacist. It would keep the profession alerted and current on any change in the status of a drug that might dictate a revision in its manner of use.

Although the Durham-Humphrey Amendment and the present labeling regulations are conducive to a close physician-pharmacist relationship, this relationship will become even more closely knit with the adoption of the proposed amended regulation.

The second category concerns those drugs regarded as being suitable for over-the-counter sale to the laity. We mentioned that the efficacy of prescription drugs had greatly improved over the past 20 years. At the same time, the efficacy of over-the-counter drugs has improved, and along with it has developed the need for a better understanding of their use. It is the philosophy of the federal law that consumers have the right to know all they need to know about a product to use it safely and intelligently. This means that when there is agreement that a particular drug can be legally labeled for over-the-counter sale, the drug will be labeled so that the lay consumer can be expected to benefit from its use—benefit in the sense that it will be both safe and efficacious.

This brings us to the question of what is adequate labeling for over-the-counter drugs. In thinking about this we are reminded of an observation expressed several years ago by the Supreme Court to the effect that the purposes of the federal law touch phases of the

lives and health of the individual which, in the circumstances of the modern industrialism, are largely beyond self-protection (*U. S. v. Dotterweich*, 320 U. S. 77). We think this observation characterizes our position that many things not within the knowledge or competence of the layman enter into adequate labeling to ensure that he may safely and effectively use over-the-counter drugs.

After much study and after many consultations with interested parties representing all phases of the pharmaceutical and allied medical fields, we republished in March of this year a list of the warning statements suggested for drugs and devices for over-the-counter sale. This list of labeling warning statements is intended as a guide to drug manufacturers and distributors for use in devising labeling which would satisfy the requirements of the Act. This list does not become a part of the law itself. The law states, under Section 502(f)(1), that a drug or device shall be deemed to be misbranded unless its labeling bears adequate directions for use and, under 502(f)(2), unless its labeling bears such adequate warnings against use in those pathological conditions or by children when its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form as are necessary for the protection of users. Therefore, this publication of the new list of warning statements is not a new concept of what constitutes appropriate or adequate labeling. The matter of self-medication is a serious one, and the public is entitled to proper instructions so it can reasonably be expected to be benefited by whatever drugs may properly come to it for unsupervised use.

Nondescript Remedies of Questionable Merit

Another matter of pertinency to pharmacists is the seemingly never-ending influx of nondescript remedies of questionable merit. All too frequently, some of you may be approached by representatives of firms offering products for over-the-counter sale which contain in their labeling many grand and glorious claims for the correction of numerous disabilities. Fortunately, most such articles are innocuous in the sense that their ingestion or other use would not, in itself, cause dire results. Unfortunately, such products often cruelly and expensively raise the hopes of the buyers, and may be harmful in the sense that they nullify the user's seeking proper medication. The law is strictly enforced and has been broadly interpreted in the courts

where it seeks to control this kind of quackery and fraud. No concoction of this type should find its way into the professional pharmacy. It is too expensive to the customer and, consequently, to the pharmacist at whatever the price. Our enforcement activities in this area of false or misleading labeling is of as great a value to you as it is to your customers. Your customer wants to believe in you and in your products. How can he do so if you fail to protect him? Our rigid enforcement of the law in this and other respects is helpful to you both.

As has been mentioned, your primary concern with the Act has to do with the dispensing of prescription drugs. However, there is a seemingly growing area in which we believe some education, or at least some dissemination of information to the pharmacist with some regulatory activity, is indicated. It concerns the repackaging of over-the-counter drugs. The law intends that the integrity of drugs be preserved all the way to the ultimate consumer. From time to time, we have encountered instances where pharmacists repackage over-the-counter items without placing adequate labeling, including directions for use and necessary warnings, on the repackaged articles. On the investigation of some injury reports, we have found that over-the-counter drugs were involved and that these were repackaged by the pharmacy. In most instances the repackaged articles failed to bear adequate information concerning the use and possible hazards of the medication. Obviously, the purposes of the law are defeated if the pharmacist repackages an over-the-counter drug and fails to transfer to the repackaged article the necessary directions for use and warnings when needed which appear on the original package. The failure to properly relabel the article constitutes a violation of the Act if the drug has been in interstate commerce. A repackaged drug is not entitled to enjoy any labeling exemption that the original product is not entitled to receive.

Although much of the law applies to drugs before they ever reach the pharmacist, I believe there is much the pharmacist can do, and is called upon to do, within the framework of the law to establish himself in a professional way as a part of the doctor-patient relationship. Fundamentally, the law is designed for the protection of the consumer. When the consumer receives the benefits of this protection, as a result of the discharge of the responsibilities placed upon you by your profession and the law, then you, too, will have benefited.

[The End]

The Scientists' Forum

Edited by BERNARD L. OSER

President and Director, Food and Drug Research Laboratories, Inc.

The following paper was presented by Kenneth Morgareidge of Food and Drug Research Laboratories, Maspeth, New York, on September 13, 1960, at the one hundred and thirty-eighth annual meeting of the American Chemical Society, held in New York. It was part of a Symposium on Analytical Methods for Food Additive and Pesticide Chemicals, under the auspices of the Pesticides Subdivision and Division of Analytical Chemistry. It is printed in the *Food Drug Cosmetic Law Journal* with the permission of the American Chemical Society.

WHEN ONE CONSIDERS the plethora of verbiage which has been expended on its interpretation since its enactment two years ago, it seems very unlikely that anyone could have anything new to say about the food-additives amendment of 1958. However, with some nine months of experience since the amendment became fully effective, it is opportune to assess our current status under it and to attempt to peer a little further into the future. As its title indicates, this discussion will be chiefly concerned with the impact of the amendment on the analytical laboratory, although there are certain related factors which will be touched on briefly.

A few simple statistics may help set the stage. In the months immediately preceding March 6 of this year (and to a considerable extent since that date), the Food and Drug Administration, at the request of industry, granted extensions in time for compliance with the provisions of the amendment covering, all told, several thousand compounds or materials. Bear in mind that in all these cases, some degree of uncertainty was thought to exist with respect to the general

recognition of safety of these substances under the conditions of intended use. Despite the fact that these extensions expire automatically as of March 6, 1961, and that there is at present no legal mechanism whereby they may be continued beyond that date, there have been submitted, as of this writing, less than 200 food-additive petitions of which some 80-odd have been accepted for filing as signified by publication of a notice in the *Federal Register*. On the basis of accepted petitions, FDA has so far issued less than 30 food-additive orders regulating the usage of less than an equivalent number of substances.

The Administration has published "white lists" of substances which are either generally recognized as safe (GRAS) or subject to valid prior sanctions. These have had the effect of reducing the number of materials subject to time extensions. However, the number whose status remains to be clarified is still rather formidable in view of the fact that the year of grace granted by the extension procedure is more than half gone. Thus, we must hopefully anticipate a steep rise in the activity curve leading to acceptance by one route or another, or we must assume that many potentially useful additives currently covered by extensions are due to be abandoned before next March.

Many factors must be considered at this stage by the proponent of an additive in reaching a decision on whether it may or may not be worth the effort and expense entailed in the preparation of an acceptable petition if this appears to be the only course whereby it may be "cleared." Quite aside from questions of its utility or its economic potential, and, also, quite aside from any question of ability to demonstrate safety under conditions of use, the problems which may arise in consequence of Section 409(b)(2)(D) cannot be ignored. This section of the Food, Drug, and Cosmetic Act (as amended) states, in connection with the requirements of a food-additive petition, that it shall contain, among other things, a "description of practicable methods for determining the quantity of such additive in or on food, and any substance formed in or on food because of its use . . . ."

Definition of a Food Additive

Here, we should pause long enough to remind ourselves of the legal definition of a food additive (Section 201(s)). It is a substance, the intended use of which "is not generally recognized among qualified experts to have been adequately shown through scientific

procedures to be safe under the conditions of its intended use." Obviously, this implies that "unsafe" conditions of use could arise, presumably as a consequence of excessive use, or use in foods in which its presence is not permitted. As a matter of practical law enforcement, therefore, the imposition of tolerances or restrictions in the food-use of any substance demands the availability of analytical or other means of detecting and/or controlling the amount present. Commissioner Larrick and other Administration officials have publicly stated that this requirement was written into the law by Congress at the suggestion of FDA as a measure necessary to protect public health, and that it had the support of the panel of scientific experts who appeared before the House Committee during the testimony which preceded the passage of the amendment.

We may add that there is no basic disagreement with this philosophy. It was accepted as a vital safeguard in the Miller Amendment governing the use of pesticides. Its extension to all food additives, including color additives, is only logical.

We should also pause to consider the scope of the definition as it applies to the source or origin of food additives. The same section (201(s)), just referred to (paraphrased), includes "any substance intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting or holding food which may reasonably be expected to become a component of food, either directly or indirectly."

Direct and Indirect Additives

It is obvious that the framers of this section just about exhausted the list of descriptive verbs applicable to any conceivable operation likely to be practiced in food production, processing and distribution. If any were omitted, it was strictly an oversight. It is also obvious that the section provides the basis for a logical division of food additives into two classes—namely, *direct* and *indirect*.

It is, perhaps, not surprising that it is the indirect additives which have been responsible for the major part of the initial confusion arising in the field, and which have absorbed a major part of the effort and time of both the administrative agencies and of industry during the past year. This is equally true for analytical chemists as it is for all others concerned. The direct or intentional additive is usually a

specific substance, available in recognized form and purity, which is used in controlled amounts to impart some clearly defined technical effect in or on the final food product. The analytical laboratory approaches the problem with a good knowledge of the chemistry involved and a fairly good idea of possible reaction products likely to result. Thus, the problem may be reasonably circumscribed at the start.

Sources of Indirect Additives

Indirect or unintentional additives, on the other hand, present a more complex set of problems. Consider for a moment the more obvious sources of these substances in foods. First, they may consist of residues of processing adjuncts or aids often employed in early stages of manufacture and which are intended to be completely removed or otherwise destroyed prior to final finishing steps. These would include bleaches, oxidizing and reducing agents, catalysts, precipitants, sequestrants, antibacterial agents and compounds used to treat process water and steam, to name just a few.

A second source of this class comprises the agricultural chemicals upon which basic food production has come to depend to a large extent. In addition to tolerances established for raw agricultural commodities under other provisions of the Food, Drug, and Cosmetic Act, food-additive orders may be required under Section 409 for residues arising from the use of soil conditioners, fertilizers, fumigants, direct pesticides, growth regulants, herbicides, dessiccants, fungicides and rodenticides.

A third group consists of residues in meats and meat products, milk and eggs which may be present therein as a consequence of the veterinary use of drugs to control livestock disease or through the use of medicated feeds as is particularly prevalent in the poultry and swine industries.

Finally, the largest potential group of indirect additives are those which may be derived from simple contact of food, with processing or storage equipment in any stage of production, or with those packaging materials in which the consumer receives the final product. The possibilities in this group are almost infinite. Most notable for its variety is the output of the packaging industry, encompassing almost every conceivable permutation and combination of the basic components fabricated by the steel, aluminum, glass, plastics, paper, textile and

lacquer industries aided and abetted by manufacturers of decorative coatings, inks, adhesives and propellants for the increasingly ubiquitous aerosol container.

Problems of Additive Analysis

The problems which confront the analytical laboratory in this field of indirect additives are manifold. In every one of the areas just discussed, the first problem is to determine, not just how much, but what has remained in or migrated to the food in question. Among the first three groups, either direct chemical conversion or metabolic processes may have resulted in a transformation to unknown substances which cannot be identified or determined by methods applicable to the original additive. The analyst does have the advantage, in many cases, of dealing with a known starting material with which he is familiar and whose chemical reactions may be at least guessed. Packaging materials, however, present a more complicated situation mainly because of the multiplicity of ingredients present in most formulations, often with ten to 15 different components represented on the make-up sheet. Even more disconcerting is the fact that many common ingredients are not single chemical entities of known structure but are mixtures of often closely related substances not economically feasible to separate, or are proprietary mixtures selected on the basis of physical properties and performance.

Assuming that through the application of skill, hard work, perseverance and not a little luck, the analyst can answer the question "what" and also arrives at an approximation of "how much" with respect to an incidental or indirect additive, he is still faced with a knotty problem. It may come as a shock to some to realize that in this context, analytical chemistry is not to be regarded as an exact science. Every analytical procedure, no matter how refined, has some finite limit with respect to the number of molecules it can detect or measure. This limit is always greater than "zero."

If the residue or migrant is present at levels substantially greater than the sensitivity limit of his method, the analyst has a positive result, and the problem of safety evaluation and tolerance passes to other hands. A negative result, on the other hand, is an indefinite one whose usefulness will depend on a number of factors, chief among which is the maximum amount of the substance sought which could

have been present but not detected under the test conditions employed. A critical evaluation of the method with respect to sensitivity, specificity and precision then becomes a highly important aspect in the evaluation of the additive.

Consequences

A little reflection will show why this is so important. If processing adjuncts or drugs or migrants from a container are not present in the food as consumed, they cannot be considered food additives and their use is thus exempt from the provisions of the law. Since the line of demarcation between what may "reasonably be expected" to become a component food and what may not is difficult to define from purely theoretical considerations, the burden of proof falls on the analytical laboratory. However, if the method employed is insensitive to the extent that a pharmacologically significant amount of the additive could have gone undetected, it is obviously worthless. One consequence of this situation is that the analytical chemist is no longer king in his own realm, but must seek counsel with those experts qualified by scientific training and experience to evaluate the safety of an additive. They will tell him just how good his methods are expected to be. "Zero" will be defined for him.

Another consequence is that as the scientific procedures of the biologist, pharmacologist and toxicologist become more refined and discriminating, the gap between the analytical and pharmacological equivalents of "zero" may be expected to become narrower in many instances. Thus, increasing pressure falls on the analyst to further explore the micro-micro frontiers of his science which inevitably leads to rapid increases in both capital-equipment and payroll budgets. A not-to-be-overlooked by-product of all this has been to give the expert analytical researcher a greater stature among his scientific peers and a new sense of self-importance.

Practical Aspects of Packaging Materials

It may be instructive to conclude this discussion with a brief examination of some practical aspects, and I will arbitrarily limit these remarks to the field of packaging materials. The broad scope of the problem has already been indicated. Let us reconsider the statutory

language already cited, namely, "a description of *practicable* methods for determining the quantity," etc., wherein I underline the word "practicable." The exact connotation intended by this word has been the subject of much discussion; and, as is often the case, an evolutionary trend is evident. In the first place, it is no longer possible to restrict its definition to exclude modern instrumental techniques. Procedures which call for ultraviolet or infrared spectrophotometry are as commonplace today as those dependent on simple colorimetery. Chromatographic separations on solid media, in vapor phase or by ion exchange are normally performed by most competent laboratories. Polarography, nuclear magnetic resonance and even mass spectrometry are well within the range of practicability. The price tag on the particular piece of hardware involved should not be considered a deterrent in the search for a practicable analytical method. The equipment should, however, be readily available from commercial sources and be capable of routine operation without undue service difficulties.

Ramsey Solvents

An entirely different meaning of "practicable" has also assumed significance in the evaluation of packaging materials. Because of the problems inherent in attempting to analyze actual foods for possible migrants from such materials as plastic films or containers, can-lining enamels or coatings on paper cartons or wrappers, such task was recognized as an impossibility even before the enactment of the present law. Collaboration between scientists in both FDA and industry resulted in agreement that it was practicable to substitute a series of relatively simple solvents which would stimulate the action of foods on the test material when maintained in contact for specified times at somewhat elevated temperatures. These solutions, often colloquially referred to as the Ramsey solvents, are currently in widespread use.

In addition to aqueous solutions of salts, acids and sugar, the list includes either lard oil or vegetable oil. Analysis of these liquid fats for often similar organic migrants was another difficult task, and it has now become recognized as practicable to substitute a pure organic solvent such as hexane or ethyl acetate for the natural fat with a knowledge that the results would be comparable, or that any uncertainty would be on the liberal side as regards migration.

A most interesting and helpful development has been the recent indication that the words "chemical" or "analytical" are not necessarily implied in conjunction with all methods of determining the quantity of an additive in or on food. If the polypropylene order (25 FR 3320) may be regarded as setting a precedent for similar packaging materials, it appears that, by administrative interpretation, compliance may be achieved through proper specification of the packaging material within limits which define it as suitable for food use. This is an entirely logical approach based on the assumption that by setting analytical specifications on the packaging material itself, which is practicable, no unsafe migratory substance will become a component of the food. The extension of this principle would greatly simplify a great many of the difficult problems now faced by the analysts. It would free several generations of chemists for more useful work.

Finally, there are other aspects of the packaging-materials field which could benefit from a somewhat more liberal interpretation of this word "practicable." The principle of the barrier layer offers an effective, practicable means of determining that the amount of a migratory additive remains below safe limits or within the range of analytical "zero." For example, it is not reasonable to expect that adhesive components used to affix a label to a glass jar or metal container would become food additives. Less obvious but equally valid are the barrier characteristics of aluminum foil, plastic films, wax coatings and a variety of other materials used in multilayer combinations. While the basic principle is recognized by both FDA and industry, the analytical laboratories still have much work to do in proving the barrier properties contingent on the thickness of many coating and laminating substances. Once this has been done, many of the present restrictions on the composition of structural and decorative components of packaging could be relaxed.

Conclusion

Quite clearly, the enactment of the food-additives amendment has placed a significant new emphasis on the importance of the analytical laboratory both for industry, in its role as petitioner, and for the enforcement agencies charged with administering the provisions of the law. It does not seem likely that this role will diminish in the foreseeable future. **[The End]**

Foreign Law Comment

By JULIUS G. ZIMMERMAN

The Latin-American Food Code

An important development in the international field of food law is the recent publication in Buenos Aires of the first official edition of the Latin-American Food Code in the Spanish language by the Permanent Latin-American Food Code Committee under the chairmanship of Dr. Carlos A. Grau.[1] The published version is the one submitted by the committee to the Seventh Latin-American Chemical Congress in Mexico City on April 3, 1959, and approved by said congress as a model Code of Food Standards for the Latin-American Republics.[2] It includes a considerable number of amendments of the preliminary draft which were inserted by the Permanent Drafting Committee in compliance with suggestions received from government officials, food scientists and food manufacturers in Latin America and in the United States.

The basic philosophy behind the Latin-American Food Code and the organization created for the purpose of revising it periodically so as to keep it in line with the progress of food technology is outlined in detail in the introduction by Dr. Grau and the resolutions adopted by the congress in Mexico City, which are reproduced in English translation in this issue of the JOURNAL. Likewise reproduced is its index, which reveals the wide scope of products covered by standards.

The Latin-American Food Code is, thus, the first model of international food standards ever completed. To what extent and how quickly the governments of Latin-American republics will incorporate

[1] Copies of this edition may be ordered from the firm Hijos de Martínez de Murguía, Córdoba 2270, Buenos Aires, Argentina, at the price of Arg. Pesos 180.00 per copy, which includes postage by surface mail.

[2] An English translation of the preliminary draft was widely circulated in the United States by The Food Law Institute and the United States Department of Commerce.

these recommended standards into their respective laws remains to be seen. It may be of special interest to American food manufacturers that the permanent Latin-American Food Code Committee pays very close attention to the current developments in the United States, particularly in respect to the approval of food additives by the Food and Drug Administration, with the view of co-ordinating the Latin-American listings to the greatest possible extent.[3]

Introduction of the Latin-American Food Code
by Carlos A. Grau

The necessity for international co-ordination in establishing definitions of the characteristics of food products and in unifying food laws and controls has been felt for a great many years (since 1894) and the subject has been debated at various international conferences and congresses.

Now that the Latin-American nations are seeking to cement their economic ties as a means of strengthening continental solidarity, the necessity and usefulness of a Latin-American Food Code have become obvious. Such a Code, in fixing uniform official requirements and uniform treatment for foods throughout Latin America, would permit the food products of one country to circulate in the others on the same conditions as in their home country. This, needless to say, would promote the development of the international food trade.

It is noteworthy that the Inter-American Council for Commerce and Production recognized at its Fourth Meeting at Lima, in November, 1952, that to expand and facilitate the circulation of foods and services it was necessary first of all to do away with unnecessary import and export restrictions and with unwarranted SANITARY REGULATIONS.

As we all know, the international trade in foods is expanding continuously. Now, since food laws are different in the different countries, their unification has become imperative in the interest not only of the consuming public, but also of the industrialists and merchants engaged in the preparation of, trade in, and export and import of foods throughout Latin America.

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[3] For further details about the historical background of the Latin-American Food Code and its counterpart in Europe, the Codex Alimentarius Europaeus, see "Progress of Foreign Food Laws" by J. G. Zimmerman in the March, 1959 issue of the FOOD DRUG COSMETIC LAW JOURNAL.

Considering the present stage of scientific development, it seems inexplicable, and even paradox, why there should still exist in the various countries and, what is worse, within one and the same country, at times profound differences in the official evaluation of a food item, especially of the conditions in which it may be suitable for consumption. This demonstrates that scientific knowledge is not being spread with the necessary rapidity. It is very important, therefore, to hold periodical scientific meetings, and very necessary to coordinate food regulations in line with the advances of food technology and hygiene so as to prevent any damages which insufficient technical knowledge on the part of officials and antiquated official provisions may cause to industry and commerce.

The existence and enactment of this Latin-American Food Code will serve not only to coordinate in all countries adopting it the control of food products, from the time when they are harvested or prepared to the time when they are shipped, exhibited, stored and sold to the consumer, but also to familiarize industrialists and merchants with the requirements of the Latin-American food laws. This will save them the effort and expense of preparing special products for export with characteristics different from those of the foods they produce for domestic consumption.

Moreover, by rationalizing manufacturing methods, the end characteristics of foods and the requisites which they must meet, the Code will contribute to lowering the prices of the exportable food production, will promote the progress of the food industry by fixing modern manufacturing and packing standards and will serve to insure fairness in commercial intercourse, thus permitting a more rapid intensification of international transactions.

Unfortunately, fraud, this child of trade and perfidy, which is as old as humanity itself, proliferates with the spreading of civilization, since—it is sad to say so—there is always someone who, placing technology at the service of deception, plots against the State which, to defend the health of its people, also uses technology, but as a means to repress frauds. In this strife, in which the eminent American food scientist Harvey W. Wiley suffered injustices when he defended truth and health, the noble and honest industry and what he called the "pure food," the present Code will form the basic legal instrument which will serve not only to punish but, still more important, to prevent and to teach how to prevent the bad technological habits which are incompatible with our health and our economy.

The First South American Chemical Congress, held at Buenos Aires in September, 1924, adopted a resolution formulated by Dr. Antonio Ceriotti who proposed that a "Codex Alimentarius Sudamericanus" be drafted by a Commission to be formed by two delegates from each of the countries attending the Congress. The Commission was formed with the appointment of Dr. Victor Copetti and Antonio Peluffo, for Uruguay; P. Bruno Guggiari and Gustavo M. Crovato, for Paraguay and Antonio Ceriotti and Tomás J. Rumi for Argentina. The Commission fulfilled its task and presented to the Second South American Chemical Congress, held at Montevideo in December, 1930, its draft of a "Codex Alimentarius Sudamericanus" which consisted of 154 articles and contained definitions of food products and several general provisions. The draft was entered on the agenda but was not debated, so that the work was nothing but a preliminary step.

At the next Latin-American Chemical Congresses, the subject came up again; although the votes always confirmed the advisability of introducing a Latin-American Food Code, no effective or concrete resolution was adopted.

At the Sixth Latin-American Chemical Congress held at Caracas from the 12th to the 19th of May, 1955, this writer again submitted a report on the matter, and after an interesting, lively and prolonged discussion, a proposal was approved and passed on to the Commission in charge of the matter which consisted of the heads of all delegations. This Commission unanimously drew up the following resolution which the Congress adopted likewise unanimously, at the second plenary session held on May 18, 1955:

The Sixth Latin-American Chemical Congress:

In ratifying the resolution adopted by the Third South American Chemical Congress held at Rio de Janeiro in 1937 and the resolutions adopted by the Fifth South American Chemical Congress held at Lima in 1951, resolves to create a Special Commission for the study of a Latin-American Food Code. This Commission shall be formed by one delegate from each country who must be a food scientist. It shall be the task of the Commission to gather information on foods from all countries and to draft a Latin-American Food Code hand in hand with the competent authorities and institutions. The Commission shall present the draft of this Code to the next Congress. It shall have its headquarters in Argentina and its chairman shall be Dr. Carlos A. Grau, who is given power to appoint the members of the Commission upon the proposal of the heads of the delegations attending said Congress.

We immediately took the necessary steps to obtain from the heads of the delegations participating in the Congress, the names of two food scientists from their country, one of whom was to be appointed

the regular member and the other the deputy member of the Special Commission. . . .

It must be noted that notwithstanding various attempts, we have not been able to obtain a reply from Costa Rica, Nicaragua, Paraguay and the Dominican Republic. For this reason, these countries are not represented on the Commission, which is regrettable. Since it took six months to form the Special Commission, the actual drafting of the Code was only begun in November, 1955.

At the time when we sent the first draft to the members of the Commission we suggested that, in the interest of our work, the co-operation of the deputy members should be enrolled.

For the same reason we pointed out that it would be helpful in special cases to consult other experts and specialized organizations, because when creating the Commission its originators had spoken of the advisability of including in the draft of the Latin-American Food Code the latest advances in food technology and the demands of the international food trade.

Considering that this Latin-American Food Code will be used in commerce between the American countries, many food products have been included which circulate on the international market. And in all cases, the requirements agreed upon defend the *standard food product* from the point of view of its biological value, in conformity with the resolution adopted at the Fifth South American Chemical Congress held at Lima in May, 1951.

Since the Latin-American Food Code is a body of doctrine and an instrument of education to be enacted in all jurisdictions, international, national, provincial, municipal and departmental, as the only way of creating coordination between them, its text states that its provisions shall be applied "by the competent authority" or "by the health authority" without naming any specific office: this point shall be defined in the food regulations to be issued by each country in harmony with the Code. This has been done with the understanding that if the requirements are identical under all jurisdictions, this will be to the benefit of public health in general and prevent differences of criterion which might unfairly prejudice industrialists and merchants. Besides it will encourage and protect the man who makes a sacrifice in order to keep his plant or his business in line with the sanitary and technological progress and to expedite the progress of all.

In the chapter relative to potable waters, no reference has been made to their hardness, because hardness is of importance only from the economic point of view, since hard water causes damage to boilers, vessels and kitchen utensils and affects laundering operations. From the nutritional point of view, however, a slight overdose of calcium and magnesium salts is beneficial, not prejudicial to the body and even helps to precipitate the excess fluor in certain waters and to retain a larger proportion of carbon dioxide in carbonated waters which are thus made more palatable.

Although the chemical composition of natural foods is not strictly constant, it nevertheless moves within certain limits, within which a food can be considered *standard*. We all know that the nature of the soil, the climate, the species and variety, the method of cultivation and harvest, etc. exercise an influence on the products of the soil, but experience has shown that the differences observed fall within certain margins. For this reason, the average percentage composition given in this Code is to serve only as a guide and has been included because of the consideration that many laboratories—especially those located far from universities—do not have at their disposal a bibliography large enough to compare the figures obtained from their analyses, so that the incorporation of these figures in the Code facilitates their task.

When the Code says "x per centum," it means "grams per 100 grams." The chemical composition of vegetables and fruits refers to their edible part, and as in the other cases, must be understood as grams per one hundred grams.

Certain new products of the food industry may possibly not comply exactly with the definitions given in the Code. Such cases must be resolved by the competent authority by way of interpretation, or by an analogical extension of the closest definition.

It must be mentioned, on the other hand, that actually, although the Code defines the genuine, standard or legal product and also determines in certain cases which products are considered first grade or fancy and which ones are ordinary, quality cannot be defined, nor is it possible to infer it from the data of an analysis, even when certain figures or coefficients correspond to a certain type of product. Quality can be proved only by specialized experts, samplers, tasters, testers. Besides, with certain exceptions, such as neutral alcohol or distilled water, the quality of foods and beverages is usually related to specific

impurities, such as those which lend a flavor and an aroma to meats, cheeses, butter, oils and particularly alcoholic beverages.

Since persons who are not sufficiently informed may ask why regulations on cosmetics, perfumes, toys, tooth pastes, textiles, desk sets, insecticides, cleansing products and certain household appliances are included in a Food Code, we will say at this point that long ago, writers and lawmakers already considered it useful to include such provisions in food laws since they cover articles used in the home, many of which are in contact with the skin, are kept next to foods and are sold at outlets which sell also foods and beverages. This is why the Swiss Ordinance of 1936 on food products included already, under the heading Objects of Everyday Use ("Objets Usuels") cosmetics, tooth pastes, toys, textiles, paints, shoe pastes, baby carriages, furniture, etc.; the Swiss Manual for Food Products fixed analysis methods for these articles; the Norwegian Regulations on Food Control, published at Oslo in 1943, contains provisions on cosmetics, etc. and why various drafts of a Codex Alimentarius have included these articles under the heading "Products of every day use and clothing."

Following the example given by Europe in 1953 the Latin-American countries decided at the conference of the U. N. Economic Commission for Latin America, held in Panama recently, to take the road of the federation with a view to hastening their industrial and commercial progress and to creating a Latin-American Common Market by first establishing free trade zones between neighboring countries. In this connection our Code will be immensely useful as far as the food trade is concerned, since when enacted it will permit competition on an even level and make sure that any products interchanged or purchased will meet common requisites and demands.

A common market for food products can exist only with a uniform doctrine on, definition and evaluation of foods. This Code belongs to all countries which have collaborated and still collaborate on it, a factor which obviously favors its adoption.

In conclusion, the present Latin-American Food Code has been drawn up in the first place to defend public health, but also to help the food industry to perfect its processes; to supply the health authorities with an up-to-date legal body that permits them to prevent, repress and punish fraudulent practices, defects and careless methods which favor or cause alterations in foods and, finally, for the purpose of advising the men who wish to obey the law and of defending them

against those who, moving on the borderline of the law, seek to increase their profits to the prejudice of the consumer's health and the consumer's pocketbook and engage in a competition that is unfair to their competitors and dangerous to the community.

Before closing we must point out that the Special Commission, of which I am Chairman, has left no stone unturned to carry out the honorable task entrusted to it by the Sixth Latin-American Chemical Congress of Caracas. I therefore wish to take this opportunity to thank the regular and the deputy members of the Commission for their excellent cooperation. I also wish to express my thanks to the persons and organizations which, having learned about our work from newspapers and magazines have offered us valuable comments. We are also extremely grateful to The Food Law Institute of New York and its late President, Dr. Charles Wesley Dunn, whose associates and collaborators have translated this Code into English and thus made it available to prominent professors, official and private institutions and interested persons in the United States of America who expressed their appreciation to us and sent us their comments.

Although the European countries have been talking about the necessity of a Codex Alimentarius Europaeus since the International Chemical Congress, held in Brussels in 1894, they have only recently agreed on drafting such a Code and begun to work on it seriously. This Latin-American Food Code is therefore the first code of its kind in the world. Its success will depend, however, on the international situation it meets and on continental solidarity.

(English translation by Ann M. Wolf, New York, New York.)

Resolutions on the Latin-American Food Code adopted unanimously by the Section on Bromatology of the Seventh Latin-American Chemical Congress, held in Mexico City in April, 1959, and passed unanimously at the Plenary Session of the Congress on April 3, 1959

1. The Congress approves the draft of the Latin-American Food Code prepared by the International Drafting Commission which had been created by the Sixth Latin-American Chemical Congress held at Caracas in 1955 and is presided by Dr. Carlos A. Grau, with a vote of applause going to the members of the Commission for the work done by them.

2. A Permanent Latin-American Food Code Commission is formed which shall have the following duties:

a. To provide for the publication of the Code and take whatever steps may be necessary for the purpose;

b. To do whatever may be necessary in order to have the Latin-American countries adopt or take into account the regulations established in the Code;

c. To receive whatever comments may be made on said regulations, and to study them with a view to accepting, modifying or rejecting them;

d. To examine whatever questions it may be asked about the interpretation of the Code;

e. If so requested, to give advice to public and/or private organizations from the Latin-American countries on everything germane to food legislation;

f. To establish bonds of mutual cooperation with professional and other organizations interested in food legislation;

g. To draft, with the assistance of whoever it considers useful, a "Manual of Analysis Methods" consistent with the Code and to provide for its publication.

3. Chairman of the Permanent Latin-American Food Code Commission shall be Dr. Carlos A. Grau. The Commission shall be composed of two food scientists from each country, the one being the regular, the other the deputy member. . . .

If a post should become vacant or has not been filled, the Chairman of the Permanent Commission shall be authorized to make the necessary appointment, upon the proposal of the respective Association of Chemists, or otherwise, upon the proposal of the competent government department.

4. Both the Chairman of the Permanent Commission and its members shall hold office until the next Latin-American Chemical Congress, on the occasion of which they shall have to render reports on their activities.

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